

1                   IN THE UNITED STATES DISTRICT COURT  
                  FOR THE NORTHERN DISTRICT OF OHIO  
2                   EASTERN DIVISION

— — —

3 IN RE: NATIONAL : HON. DAN A. POLSTER  
4 POLSTER  
PRESCRIPTION OPIATE :  
5 LITIGATION :  
:  
6 APPLIES TO ALL CASES : NO.  
: 1:17-MD-2804

- HIGHLY CONFIDENTIAL -

8 SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

— — —

9 JANUARY 17, 2019

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10 VOLUME II

Videotaped sworn continued deposition of TRACEY L. NORTON, taken pursuant to notice, was held at BEST WESTERN LEHIGH VALLEY HOTEL & CONFERENCE CENTER, 300 Gateway Drive, Bethlehem, Pennsylvania, beginning at 8:38 a.m., on the above date, before Margaret M. Reihl, a Registered Professional Reporter, Certified Shorthand Reporter, Certified Realtime Reporter, and Notary Public.

— — —

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<p style="text-align: right;">Page 550</p> <p>1 A P P E A R A N C E S: (cont'd)</p> <p>2</p> <p>3 KIRKLAND &amp; ELLIS LLP</p> <p>4 BY: JENNIFER G. LEVY, ESQUIRE</p> <p>5 655 Fifteenth Street, N.W.</p> <p>6 Washington, D.C. 20005</p> <p>7 (202) 879-5211</p> <p>8 jennifer.levy@kirkland.com</p> <p>9 Representing the Defendant Allergan</p> <p>10</p> <p>11 REED SMITH LLP</p> <p>12 BY: LOUIS W. SCHACK, ESQUIRE</p> <p>13 Three Logan Square</p> <p>14 1717 Arch Street, Suite 3100</p> <p>15 Philadelphia, Pennsylvania 19103</p> <p>16 (215) 851-8280</p> <p>17 lschack@reedsmith.com</p> <p>18 Representing the Defendant AmerisourceBergen</p> <p>19</p> <p>20 FOLEY &amp; LARDNER LLP</p> <p>21 BY: KATY E. KOSKI, ESQUIRE</p> <p>22 111 Huntington Avenue</p> <p>23 Boston, Massachusetts 02199-7610</p> <p>24 (617) 342-4000</p> <p>kkoski@foley.com</p> <p>Representing the Defendant Anda</p> <p>17 MORGAN LEWIS &amp; BOCKIUS LLP</p> <p>18 BY: MARTHA A. LEIBELL, ESQUIRE</p> <p>19 200 South Biscayne Boulevard</p> <p>20 Suite 5300</p> <p>21 Miami, Florida 33131-2339</p> <p>22 (305) 415-3387</p> <p>23 martha.leibell@morganlewis.com</p> <p>24 Representing the Defendant Teva</p>	<p style="text-align: right;">Page 552</p> <p>1 TELEPHONIC APPEARANCES:</p> <p>2 JONES DAY</p> <p>3 BY: KASEY M. HEMPHILL, ESQUIRE</p> <p>4 555 South Flower Street</p> <p>5 Fiftieth Floor</p> <p>6 Los Angeles, California 90071-2300</p> <p>7 (213) 243-2356</p> <p>8 Representing the Defendant Walmart</p> <p>9</p> <p>10 TUCKER ELLIS LLP</p> <p>11 BY: RACHEL N. BYRNES, ESQUIRE</p> <p>12 950 Main Avenue, Suite 1100</p> <p>13 Cleveland, Ohio 44113</p> <p>14 (216) 696-3950</p> <p>15 rachel.byrnies@tuckerellis.com</p> <p>16 Representing the Defendants</p> <p>17 Janssen and J&amp;J</p> <p>18</p> <p>19 ARNOLD &amp; PORTER KAYE SCHOLER LLP</p> <p>20 BY: DAVID D. FAUVRE, ESQUIRE</p> <p>21 601 Massachusetts Ave, NW</p> <p>22 Washington, DC 20001-3743</p> <p>23 (202) 942-5000</p> <p>24 david.fauvre@arnoldporter.com</p> <p>Representing the Defendants, Endo</p> <p>Health Solutions; Endo</p> <p>Pharmaceuticals, Inc.; Par</p> <p>Pharmaceutical Companies, Inc. f/k/a</p> <p>Par Pharmaceutical Holdings, Inc.</p>

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1 THE VIDEOGRAPHER: We're now on  
2 the record. My name is Phillip Todd,  
3 I'm a videographer for Golkow Litigation  
4 Services. Today's date is January 17,  
5 2019. The time is 8:38 a.m.

6 This video deposition is being  
7 held in Bethlehem, PA in the matter of  
8 National Prescription Opiate Litigation  
9 for the United States District Court,  
10 Northern District of Ohio, Eastern  
11 Division. The deponent is Tracey  
12 Norton. Counsel will be noted on the  
13 stenographic record.

14 The court reporter is Peg Reihl  
15 and will now swear in the witness.  
16 ... TRACEY L. NORTON, having been  
17 duly sworn as a witness, was examined  
18 and testified further as follows:

19 BY MS. VANNI:  
20 Q. Good morning, Tracey.  
21 A. Good morning.  
22 Q. Can you please introduce yourself  
23 to the jury.  
24 A. Yes, my name is Tracey Norton.

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1 Q. We've seen some documents over  
2 the course of the last couple of days where you  
3 were referred to as Tracey Hernandez.  
4 Is that a previous name you used  
5 to use?  
6 A. Yes, it is.  
7 Q. What is your educational  
8 background?  
9 A. I have a Bachelor's in business  
10 from Muhlenberg University and a Master's in  
11 pharmaceutical policy from the University of  
12 Florida.  
13 Q. And when did you earn your  
14 Master's?  
15 A. In -- my Master's was 2010.  
16 Q. How long did it take you to earn  
17 your Master's?  
18 A. Two years.  
19 Q. And can you give us a sense of  
20 what your Master's involves.  
21 A. Yes. It covered all different  
22 types of regulations that apply to the  
23 pharmaceutical industry, so FDA regulations,  
24 drug approval, DEA regulations, state

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1 regulations, basically the gamut of regulations  
2 that apply to the industry.

3 Q. And why did you get your  
4 Master's?

5 A. It was an area that I wanted to  
6 pursue and make sure that I had a thorough  
7 understanding, even beyond DEA compliance.

8 Q. When did you first begin working  
9 at Qualitest?

10 A. In August of 2011.

11 Q. And when did you leave Qualitest?

12 A. In December of 2014.

13 Q. So you were there about three  
14 years and a couple of months?

15 A. Yes, three years and four months.

16 Q. What was Qualitest's customer  
17 base?

18 A. Primarily wholesalers and chains.

19 Q. And when you say "chains," what  
20 are you referring to?

21 A. Chain drug stores.

22 Q. When you joined Qualitest, what  
23 was your position?

24 A. The director of DEA compliance.

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1 Q. And during your time at  
2 Qualitest, did your position change?

3 A. No.

4 Q. As director of DEA compliance,  
5 can you explain to us a little bit of what you  
6 were responsible for on a day-to-day basis?

7 A. Absolutely. I was responsible  
8 for -- excuse me -- quota, recordkeeping, such  
9 as dealing with DEA 222 forms, import and export  
10 documentation, also end of year reporting, ARCOS  
11 reporting, SOMS and training for employees.

12 Q. Did anyone report to you?

13 A. Yes. Ultimately, I had eight  
14 people that reported to me. When I first  
15 started there was one.

16 Q. And just, generally speaking,  
17 what were the functions of those people who  
18 reported to you?

19 A. So I had a person for each --  
20 each manufacturing and distribution facility,  
21 and they were responsible for the overall  
22 compliance of that facility, all of the  
23 activities that I mentioned, the day-to-day  
24 records and things like that.

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1 And then I also had a SOMS team  
2 of SOMS manager and two associates.

3 Q. So SOMS was handled separately?

4 A. Yes, separate from the  
5 manufacturing and distribution.

6 Q. I want to talk to you about some  
7 of the components of DEA compliance program at  
8 Qualitest based on what you just told us that  
9 you handled on a day-to-day basis.

10 A. Sure.

11 Q. I believe one thing you just  
12 mentioned was quota, so I want to talk to you  
13 first a little about quota, okay?

14 A. Mm-hmm, yes.

15 Q. Before I do that, I want to ask  
16 you whether you recall being shown a  
17 demonstrative that plaintiff's counsel put

18 together yesterday, it's Exhibit 4. I think you  
19 have it in front of you.

20 A. Yes, I do.

21 Q. It's called "Par Total Pills  
22 Shipped 2008 - 2015."

23 A. Yes.

24 Q. Do you remember that?

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1 A. Yes, I do.

2 Q. Counsel represented to you  
3 yesterday that the information in this  
4 demonstrative was based on information that Endo  
5 had pointed him to.

6 Do you recall that?

7 A. I do.

8 Q. Have you ever seen any of the  
9 underlying data referenced in this  
10 demonstrative?

11 A. No, I have not.

12 Q. Do you know what the data  
13 represents?

14 A. No.

15 Q. Do you know if the data reflects  
16 sales?

17 A. I'm not sure.

18 Q. You mentioned yesterday that it  
19 could reflect more than sales.

20 Do you have a recollection of  
21 that?

22 A. Yes, yes, it could actually also  
23 reflect transfers, when DEA refers to a sale  
24 that can also be a transfer or a movement of

<p style="text-align: right;">Page 561</p> <p>1 product from your facility to somewhere else.</p> <p>2 MR. BUCHANAN: Move to strike,</p> <p>3 called for speculation. The witness'</p> <p>4 answer was speculation.</p> <p>5 BY MS. VANNI:</p> <p>6 Q. Are you familiar with quota --</p> <p>7 A. Yes.</p> <p>8 Q. -- and how quota is handled?</p> <p>9 A. Yes, I am.</p> <p>10 Q. Do you know if this demonstrative</p> <p>11 is accurate?</p> <p>12 A. No, I do not.</p> <p>13 Q. Counsel also referred to</p> <p>14 Qualitest as pumping pills out.</p> <p>15 Do you recall that?</p> <p>16 A. I do.</p> <p>17 Q. Can you describe for the jury</p> <p>18 what quota is?</p> <p>19 A. Yes. So quota is a requirement</p> <p>20 by DEA, it's basically a permission to purchase</p> <p>21 a certain -- in Qualitest's case, it was a</p> <p>22 permission to purchase a certain quantity of raw</p> <p>23 material for each controlled substance family.</p> <p>24 DEA regulates that amount every year, there's a</p>	<p style="text-align: right;">Page 563</p> <p>1 different departments at Qualitest to find out</p> <p>2 what the needs of the department were. So if</p> <p>3 there were any research projects that were going</p> <p>4 on, if there were any transfers or validations</p> <p>5 that were going on.</p> <p>6 So, for example, if product was</p> <p>7 being made in one piece of equipment and needed</p> <p>8 to be transferred to a different piece of</p> <p>9 equipment, you would have to make three</p> <p>10 validation batches, that was an FDA requirement,</p> <p>11 so we would need to get quota for that as well.</p> <p>12 We would also have information on</p> <p>13 destructions and information on sales, and we</p> <p>14 would be submitting all of that information to</p> <p>15 DEA and also answering any follow-up questions</p> <p>16 that they had on those quotas.</p> <p>17 Q. How often would you have to apply</p> <p>18 for quota?</p> <p>19 A. You would apply in April of the</p> <p>20 prior year for the current year. That was your</p> <p>21 initial submission, and then throughout the</p> <p>22 year, as things changed, you would submit</p> <p>23 additional quota requests if sales increased.</p> <p>24 You could also surrender quota if you weren't</p>
<p style="text-align: right;">Page 562</p> <p>1 new quota assigned, and it's based on several --</p> <p>2 several different things that DEA considers,</p> <p>3 information that the company provides as well as</p> <p>4 information that DEA obtains elsewhere.</p> <p>5 Q. Like what?</p> <p>6 A. It's based on sales data that the</p> <p>7 company provides. It's also based on</p> <p>8 destruction data of material that's on hand.</p> <p>9 It's based on prescriptions written, DEA does</p> <p>10 review the IMS data that talks about</p> <p>11 prescriptions and, you know -- so they're</p> <p>12 looking for the medical need for the product.</p> <p>13 It's also -- they also confer</p> <p>14 with FDA on it as well, and it could also be for</p> <p>15 commercial distribution, but the quota is also</p> <p>16 used for research activities as well, validation</p> <p>17 activities of validating new processes and</p> <p>18 things like that.</p> <p>19 Q. As part of your responsibilities</p> <p>20 as DEA compliance manager, did you manage quota?</p> <p>21 A. Yes.</p> <p>22 Q. And what would that require you</p> <p>23 to do?</p> <p>24 A. We would interact with a lot of</p>	<p style="text-align: right;">Page 564</p> <p>1 using it.</p> <p>2 Q. Could it be carried over?</p> <p>3 A. No, it could not. It was</p> <p>4 basically for that one year, and anything that</p> <p>5 was not used in the permission by December 31st</p> <p>6 was forfeited.</p> <p>7 Q. Approximately how much of your</p> <p>8 time was spent managing quota?</p> <p>9 A. Probably about 40%.</p> <p>10 Q. And as part of your</p> <p>11 responsibilities in managing quota, would you</p> <p>12 communicate with the DEA?</p> <p>13 A. Yes, on a regular basis, mostly</p> <p>14 with DEA headquarters.</p> <p>15 Q. Based on your experience and</p> <p>16 knowledge of how quota works, could Qualitest</p> <p>17 just be pumping pills out, as counsel suggested?</p> <p>18 A. No.</p> <p>19 MR. BUCHANAN: Objection to form.</p> <p>20 BY MS. VANNI:</p> <p>21 Q. Why is that?</p> <p>22 A. DEA basically regulates how much</p> <p>23 we can make, and, again, it's based on a number</p> <p>24 of factors, one of which is medical need.</p>



<p style="text-align: right;">Page 565</p> <p>1 Q. You also mentioned, I believe you 2 said recordkeeping or end of year recordkeeping 3 reporting. 4 Can you tell the jury what that 5 is? 6 A. Yes. So every transfer that we 7 have of a Schedule I or II drug, which is what 8 oxycodone or hydrocodone was, every movement 9 that we make of those drugs is visible to DEA. 10 There's a form called a DEA 222 form, which is a 11 three-part form issued by DEA. The purchaser 12 receives a copy, the supplier receives a copy, 13 and DEA gets a copy. So they're aware of every 14 movement and every customer purchase of Schedule 15 I or Schedule II drugs. So that's the 222s. 16 Then we also did ARCOS reporting, 17 which is a quarterly report, could also be 18 monthly, depending on how the company wants to 19 submit it, but it's a quarterly report that sums 20 up all sales, all purchases. And by "sales," I 21 mean movement as well as actual sales. All 22 purchases, all transfers that we would make 23 within the company or externally, all of that is 24 recorded and submitted to DEA on a regular</p>	<p style="text-align: right;">Page 567</p> <p>1 investigate and you'll have to explain if you 2 can't account for everything. 3 Q. If you're not able to reconcile 4 your numbers, what do you have to do? 5 MR. BUCHANAN: Objection to form, 6 calls for narrative. 7 THE WITNESS: You would have to 8 report it to DEA if you can't reconcile, 9 and there could be a violation. 10 BY MS. VANNI: 11 Q. You were asked some questions 12 yesterday about the SOMS program at Qualitest. 13 Do you recall that? 14 A. Yes. 15 Q. First of all, can you define what 16 SOMS is? 17 A. Suspicious order monitoring 18 system. 19 Q. And why is -- is a SOMS program 20 important, in your view? 21 A. It is, yes. 22 Q. And why? 23 A. Because we need to make sure that 24 we're shipping product to customers that are</p>
<p style="text-align: right;">Page 566</p> <p>1 basis. So, again, they have additional 2 information about your movements. 3 And then at the end of the year, 4 we also did an end of year report, and that was 5 a full accountability of everything on site 6 of -- a large part of that is your end of year 7 inventory, and you count everything on site, and 8 then you reconcile to the prior year's 9 inventory, and that gets submitted to DEA as 10 well. 11 MR. BUCHANAN: Move to strike the 12 narratives, and, frankly, they should 13 proceed in a question, answer not with 14 narratives. 15 BY MS. VANNI: 16 Q. And why is end of year reporting 17 important? 18 A. It's important because it's a 19 total reconciliation and it shows that you are 20 able to account for all of your product. There 21 is some loss that's allowed by DEA, because they 22 expect that you're going to have some 23 manufacturing loss due to the processes, but 24 there's an unspoken percentage that DEA will</p>	<p style="text-align: right;">Page 568</p> <p>1 legitimate and that have legitimate use of the 2 product. 3 Q. You were asked some questions 4 yesterday about a DEA meeting that Qualitest had 5 in March of 2013. 6 Do you recall those? 7 A. I do. 8 Q. And I believe that counsel made 9 some reference to Qualitest being called to or 10 summoned to the DEA in DC, and I think you 11 referred to it as a different kind of meeting. 12 Can you describe the meeting that 13 Qualitest had with DEA in March of 2013? 14 A. Yes. 15 MR. BUCHANAN: Objection, 16 misstates the record. 17 THE WITNESS: DEA had a 18 distributor initiative that was ongoing 19 for several years, and it was their 20 intent to meet with all distributors, 21 all distributor registrants and to share 22 information, and it was really a meeting 23 where they were talking to industry 24 about some possible things that they</p>

<p style="text-align: right;">Page 569</p> <p>1 could look at to improve their SOMS 2 program, as well as getting information 3 from industry as to what tools might be 4 out there, what they were doing that 5 could also be of value. Really looking 6 to partner to -- to help make the SOMS 7 programs the best it could be. 8 MR. BUCHANAN: Objection, move to 9 strike, lack of foundation. 10 BY MS. VANNI: 11 Q. Did you personally attend the 12 meeting? 13 A. I did. 14 Q. Did you interact with DEA at the 15 meeting? 16 A. I did, yes. 17 Q. Counsel showed you a variety of 18 documents yesterday to establish that you knew 19 about certain factors that went into having an 20 effective SOMS program. 21 Before you met with the DEA in 22 March of 2013, do you remember that line of 23 questioning? 24 A. Yes, I do.</p>	<p style="text-align: right;">Page 571</p> <p>1 to strike, absence of foundation. 2 BY MS. VANNI: 3 Q. And when you started at 4 Qualitest, were there some areas of improvement 5 that you wanted to address with respect to the 6 SOMS program? 7 A. Yes, there were. 8 Q. Okay. And what were some of 9 those areas? 10 A. I had heard at DEA conferences 11 that there were things that DEA thought that 12 industry could do to improve SOMS programs, such 13 as a customer questionnaire, a customer on-site 14 visits, putting boots on the ground, to visit 15 your customers, SOPs, chargeback data. Those 16 were all things that had come up at DEA 17 conferences in the past and that DEA was 18 suggesting could be helpful. 19 Q. Were they required by regulation? 20 A. They were not. 21 MR. BUCHANAN: Objection to form, 22 foundation. 23 BY MS. VANNI: 24 Q. Are you familiar with the</p>
<p style="text-align: right;">Page 570</p> <p>1 Q. In fact, I believe counsel's 2 question was something to the effect of you knew 3 what was important before the DEA meeting in 4 2013, right? 5 MR. BUCHANAN: Objection to form. 6 THE WITNESS: Yes. 7 BY MS. VANNI: 8 Q. Do you recall that? 9 A. I do. 10 Q. In fact, that's true, right? 11 A. It is very true. 12 Q. Is there any dispute about that? 13 A. No, not at all. 14 Q. Do you have an understanding, as 15 you sit here today, why Qualitest hired you in 16 2011? 17 A. I do. 18 Q. What is that? 19 A. Qualitest hired me to come in and 20 make improvements to the DEA program that they 21 wanted to have, and that includes all of the 22 recordkeeping quotas, SOMS, make improvements 23 across the board. 24 MR. BUCHANAN: Objection. Move</p>	<p style="text-align: right;">Page 572</p> <p>1 regulation? 2 A. I am, yes. 3 Q. I want to show you what plaintiff 4 used yesterday, I believe it was Exhibit 17. I 5 think you have it in front of you. 6 If you could go to I believe it's 7 page 574.24. 8 A. Yes. 9 Q. Under "Potential Failure 10 Mode/Effect." 11 Do you see where I am? 12 A. I do. 13 Q. It says, "Our current Suspicious 14 Order Monitoring Program (SOMS) was built in 15 pieces and only applies to the retail side of 16 the business." 17 A. Yes. 18 Q. "DEA requires it to apply to all 19 customers. In addition, the current system has 20 had two issues in the past year that resulted in 21 controlled product being released that should 22 not have been. The system needs to be revamped, 23 all customers added, IMS data and chargeback 24 data incorporated and eventually a contracted</p>

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1 customer assessment firm hired or an on-site  
2 SOMS specific individual to perform these  
3 assessments."  
4 Do you know who wrote this?  
5 A. I did.  
6 Q. Yesterday counsel had suggested  
7 to you that this document was written in  
8 January 2013 because it was attached to an  
9 e-mail from that date.  
10 Do you recall that?  
11 A. Yes, I do.  
12 Q. When was this document written?  
13 A. This document was a living  
14 document that was written from -- started at the  
15 time when -- at the time that I was hired and as  
16 I reviewed different areas, I added to the  
17 document, on an ongoing basis.  
18 Q. And what was the purpose of you  
19 doing that?  
20 A. To document things that I wanted  
21 to improve at the company and to basically make  
22 sure that we addressed all of them.  
23 Q. Your comments with respect to the  
24 current suspicious order monitoring program that

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1 I just read, were they -- was that based on  
2 observations that you made?  
3 A. It was.  
4 Q. Can you estimate for us when you  
5 started looking at the SOMS program at  
6 Qualitest?  
7 A. Basically --  
8 MR. BUCHANAN: Calls for  
9 speculation.  
10 THE WITNESS: -- when I started.  
11 BY MS. VANNI:  
12 Q. And I think we've established  
13 that you started in 2011. Do you remember the  
14 month?  
15 A. August of 2011, yes.  
16 Q. Tracey, did you wait until the  
17 DEA meeting in March 2013 to start looking at  
18 the SOMS program?  
19 A. Absolutely not.  
20 Q. If you started looking at the  
21 SOMS program around the time you were first  
22 hired at Qualitest, can you explain to the jury  
23 why all of the changes that you wanted to make  
24 were not implemented before March 2013?

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1 A. Yes.  
2 MR. BUCHANAN: Objection,  
3 foundation.  
4 THE WITNESS: Creating a SOMS  
5 program is an extremely involved  
6 process, especially if you want to do it  
7 right, and our -- we had to evaluate the  
8 electronic systems that were available  
9 to us, our own internal system to see if  
10 it was capable of handling and our IT  
11 structure to see if they could build --  
12 we could build our own system in-house  
13 versus outsource it. We had to hire  
14 people to manage the program on a  
15 regular basis. We had to write SOPs.  
16 We had to educate internal people on  
17 what the program was about and how to  
18 use it. And we had to make sure that we  
19 had the capability to visit customers.  
20 We had to review chargeback data. There  
21 were a lot of different things that went  
22 into developing an enhancement of that  
23 program.  
24

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1 BY MS. VANNI:  
2 Q. You mentioned needing to hire  
3 people?  
4 A. Yes.  
5 Q. Were you involved in the hiring  
6 process?  
7 A. I was.  
8 Q. Can you describe a little bit for  
9 us why that would take time?  
10 A. It took a long time because of  
11 the facility being in Huntsville, for one. It  
12 was not -- not really in the pharmaceutical  
13 belt, so it was a little bit difficult to find  
14 someone who had applicable experience and then,  
15 also, we wanted to -- I wanted to make sure that  
16 we found the right person. I think it's a very  
17 important role. So it definitely took a long  
18 time to get the right person in and to write the  
19 job descriptions as well.  
20 Q. With respect to the DEA meeting  
21 that you were questioned about yesterday, you  
22 made a comment or provided testimony that  
23 counsel moved to strike that the SOMS -- that  
24 the DEA did not find Qualitest SOMS program



<p style="text-align: right;">Page 577</p> <p>1 inadequate.</p> <p>2 Do you recall that?</p> <p>3 A. I do, yes.</p> <p>4 Q. Do you want to say something now</p> <p>5 about the DEA's findings with respect to</p> <p>6 Qualitest's SOMS programs, based on your</p> <p>7 presence at that meeting?</p> <p>8 A. Yes, yes, I do.</p> <p>9 MR. BUCHANAN: Objection, calls</p> <p>10 for speculation. Lack of foundation.</p> <p>11 THE WITNESS: The SOMS program --</p> <p>12 the SOMS programs was not in violation</p> <p>13 of the DEA regulations. If it was in</p> <p>14 violation of the DEA regulations, we</p> <p>15 would have gotten a fine and/or a letter</p> <p>16 of admonition, and that was not the</p> <p>17 case.</p> <p>18 Again, this was a meeting of</p> <p>19 exchanging ideas and information.</p> <p>20 BY MS. VANNI:</p> <p>21 Q. Following the meeting with DEA,</p> <p>22 did you continue to try to enhance the SOMS</p> <p>23 programs at Qualitest?</p> <p>24 A. Yes, we continued on the path</p>	<p style="text-align: right;">Page 579</p> <p>1 manager. We also hired two associates to work</p> <p>2 for him to review orders on a daily basis.</p> <p>3 Q. Did you take any actions in</p> <p>4 trying to elicit information from customers?</p> <p>5 A. We did. We also submitted a --</p> <p>6 created a customer questionnaire, which we had</p> <p>7 started previously, but it was an ongoing</p> <p>8 activity, and we added some additional questions</p> <p>9 to it and sent that out as well.</p> <p>10 Q. And what type of information did</p> <p>11 you ask for in those questionnaires?</p> <p>12 A. We asked for information about</p> <p>13 our customers, licensing, which we already knew</p> <p>14 that they had valid licenses, but we wanted more</p> <p>15 detail so that we could actually go online. We</p> <p>16 wanted information about their state licenses so</p> <p>17 we could check their regulatory history online.</p> <p>18 We also wanted names of owners or</p> <p>19 people that worked at the facility, information</p> <p>20 about the customer's SOM program, what they were</p> <p>21 doing. Information about the expected</p> <p>22 purchases, products, the product mix that they</p> <p>23 were -- would be purchasing from us. Yeah,</p> <p>24 that's pretty much a lot of information.</p>
<p style="text-align: right;">Page 578</p> <p>1 that we had been on and incorporated several of</p> <p>2 the things -- actually all of the things that</p> <p>3 DEA had suggested.</p> <p>4 Q. Can you give us a sense of some</p> <p>5 of the things that you implemented following</p> <p>6 that meeting?</p> <p>7 A. Yes, we implemented -- we</p> <p>8 continued to complete our SOPs, writing SOPs.</p> <p>9 We educated employees, the sales team, our</p> <p>10 employees that we hired on the system and how to</p> <p>11 work the system, how to run it, and, also, we</p> <p>12 even did training for warehouse people, which</p> <p>13 was above and beyond and was really something</p> <p>14 that we thought would be helpful to have another</p> <p>15 set of eyes on orders that were going out. We</p> <p>16 did implement the customer visits. We</p> <p>17 contracted with a company to do some of those</p> <p>18 visits, as well as our SOMS manager also did</p> <p>19 some. And we contracted with an IT company to</p> <p>20 implement the statistical analysis system,</p> <p>21 electronic system.</p> <p>22 Q. Did you make any hires following</p> <p>23 the meeting?</p> <p>24 A. We did. We hired the SOM</p>	<p style="text-align: right;">Page 580</p> <p>1 Q. Yesterday you were shown</p> <p>2 Plaintiffs' Exhibit Number 5. You should have</p> <p>3 it in front of you. I can direct your attention</p> <p>4 to the second page of that document on Qualitest</p> <p>5 letterhead dated October 18, 2013?</p> <p>6 A. Yes.</p> <p>7 Q. Turn the back page of it, 594.4,</p> <p>8 is that your signature?</p> <p>9 A. Yes, it is.</p> <p>10 Q. Did you send this letter?</p> <p>11 A. I did.</p> <p>12 Q. What is -- what was the purpose</p> <p>13 in you sending this letter?</p> <p>14 A. The purpose of the letter was to</p> <p>15 notify our customers that we were going to be</p> <p>16 asking for additional information from them in</p> <p>17 the form of a questionnaire, that we were</p> <p>18 concerned we would be looking at orders in</p> <p>19 different ways than we had in the past and --</p> <p>20 Q. Different how?</p> <p>21 A. Different through the new</p> <p>22 electronic system, so those -- the information</p> <p>23 that the new electronic system would give us</p> <p>24 would be additional information. We may be</p>

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1 coming back to the customers to ask questions,  
 2 and so it was really just notifying them that,  
 3 you know, they might get calls from us that they  
 4 did have to fill out this questionnaire,  
 5 basically putting them on alert to this change.  
 6 Q. If the customers did not fill out  
 7 questionnaires, would you take any steps or  
 8 actions or would anybody in your department?  
 9 A. Yes, we would follow up with them  
 10 at first to give them an opportunity. If it  
 11 didn't -- hadn't been sent to the correct  
 12 person, we wanted to make sure that it  
 13 absolutely did get to the right person. If they  
 14 didn't fill it out after that, then we would  
 15 take action against them as far as not servicing  
 16 them.  
 17 Q. If I could direct your attention  
 18 to the third paragraph, it's the second sentence  
 19 begins, "Qualitest is enhancing its due  
 20 diligence efforts when fulfilling orders to  
 21 provide greater assurance that our products are  
 22 purchased by appropriate patients for prescribed  
 23 uses."  
 24 Did I read that correctly?

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1 A. Yes, you did.  
 2 Q. What did you mean by that  
 3 statement?  
 4 A. We wanted to make sure that we  
 5 were doing everything we could, meeting the  
 6 regulation, which is what we were doing  
 7 previously, but we also wanted to make sure that  
 8 we were building in some of the things that I  
 9 knew had been suggestions and feedback from DEA  
 10 in the past to make sure that we were doing  
 11 whatever we could to prevent our product from  
 12 getting into illegitimate hands.  
 13 Q. And I think we established you're  
 14 familiar with the DEA regulations?  
 15 A. Yes.  
 16 Q. The things that you were able to  
 17 implement during your time at Qualitest with  
 18 respect to the SOMS program, were they required  
 19 under the regulation?  
 20 MR. BUCHANAN: Objection to the  
 21 form, foundation.  
 22 THE WITNESS: No, they were not  
 23 required.  
 24 BY MS. VANNI:

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1 Q. I believe you mentioned customer  
 2 visits as well?  
 3 A. Yes.  
 4 Q. Were you able to implement  
 5 customer visits after the DEA meeting?  
 6 A. We were, yes.  
 7 Q. And why did you want to do that?  
 8 A. It was one of the suggestions  
 9 that DEA had had, and I had seen it being  
 10 suggested by DEA previously as well.  
 11 Q. With respect to Qualitest SOMS  
 12 program, if an order of interest was flagged,  
 13 what would happen?  
 14 MR. BUCHANAN: Objection as to  
 15 time.  
 16 THE WITNESS: There would be an  
 17 investigation into that order. We would  
 18 look at the customer's history, purchase  
 19 history. We would go back to the  
 20 questionnaire and look at the  
 21 information that had been submitted. We  
 22 would do additional research into the  
 23 information on the questionnaire to make  
 24 sure nothing had changed. We would also

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1 get the customer's feedback on, you  
 2 know, why there was an increase. If  
 3 that did not sound justified, we would  
 4 not ship the order and notify DEA.  
 5 If other information was  
 6 available that made us feel that the  
 7 customer needed an additional visit, we  
 8 would revisit the customer. Ultimately,  
 9 we would either discontinue the order  
 10 and notify DEA. We would let the order  
 11 go through if everything was okay, or in  
 12 some cases, we would discontinue the  
 13 customer.  
 14 BY MS. VANNI:  
 15 Q. If you didn't hear back from the  
 16 customer, receive information that you needed,  
 17 what would happen?  
 18 A. We would follow up, try to get  
 19 that information. If we still did not get the  
 20 information, we would --  
 21 MR. BUCHANAN: Excuse me. Same  
 22 objection as to time.  
 23 THE WITNESS: -- we would  
 24 eventually cut off the customer.

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1 BY MS. VANNI:  
 2 Q. And what time frame are we  
 3 talking about here with respect to your  
 4 description of the SOMS program, as you just  
 5 provided it?  
 6 A. As far as when did the customer  
 7 visits start?  
 8 Q. No, in terms of the questions  
 9 that I was just asking you generally in terms of  
 10 the SOMS program, how it operated, what time  
 11 frame are you referring to?  
 12 A. So the time frame of an order  
 13 pending versus the investigation and all the  
 14 happenings, so it --  
 15 Q. My question was a little bit  
 16 different.  
 17 What years are we talking about  
 18 that the SOMS program operated like this?  
 19 A. Basically 2013, 2014.  
 20 Q. You also when you were describing  
 21 your overall DEA compliance responsibilities at  
 22 Qualitest, you had mentioned training?  
 23 A. Yes.  
 24 Q. What do you mean by "training"?

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1 A. We did a lot of training for  
 2 employees, a lot of different types of training.  
 3 So the main one was the general  
 4 overview, which covered I called it soup to nuts  
 5 on the DEA regulations, all of the  
 6 recordkeeping, the requirements, storage  
 7 requirements, the general overview of quota, the  
 8 need for the suspicious order monitoring. It  
 9 covered everything.  
 10 MR. BUCHANAN: Objection to form  
 11 as to time again. I'm sorry it's  
 12 belated, but if you want to correct it  
 13 to clarify, I just wanted to give you  
 14 notice.  
 15 BY MS. VANNI:  
 16 Q. When would you have implemented  
 17 training?  
 18 A. Basically when I started.  
 19 Q. So we're talking like the 2011  
 20 time frame?  
 21 A. Correct.  
 22 Q. And would the training be  
 23 provided at different points in time?  
 24 A. It would, yes. It was provided

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1 on an ongoing basis across the employee.  
 2 Q. Would you personally provide the  
 3 training, or would people on your team do it?  
 4 A. At first I was the main one  
 5 providing the training. Certain specific  
 6 training others gave, so, for example, our SOM  
 7 manager gave specific SOMS training.  
 8 Q. What kind of -- what's your  
 9 understanding of what training Mr. Brantley  
 10 would provide?  
 11 A. Basically, why we needed the SOMS  
 12 program.  
 13 MR. BUCHANAN: Objection to form,  
 14 foundation.  
 15 THE WITNESS: What types of  
 16 things we would look for and why it was  
 17 important, things that we would  
 18 document.  
 19 BY MS. VANNI:  
 20 Q. Prior to someone on your team  
 21 giving training to someone in the company, would  
 22 you have a discussion with them?  
 23 A. We were discussing things with  
 24 employees all the time, so it was really an

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1 ongoing education process, so we would train and  
 2 talk to all employees, all levels.  
 3 Q. Finally, you were asked some  
 4 questions yesterday about some industry groups  
 5 that you belong to, specifically the  
 6 anti-diversion working group and the New Jersey  
 7 Pharmaceutical Industry Group.  
 8 Do you remember that?  
 9 A. I do, yes.  
 10 Q. Can you describe for the jury  
 11 what the anti-diversion working group is?  
 12 A. Yes, the anti-diversion working  
 13 group was put together -- it consisted of  
 14 manufacturers and distributors, it was a group  
 15 that met maybe four times total. It --  
 16 Q. What was the purpose of the  
 17 group?  
 18 A. The purpose of the group was to  
 19 collaborate, to see if there was a way that we  
 20 could impact abuse and diversion in a positive  
 21 way, to help to prevent it, and we came up with  
 22 the red flags video.  
 23 Q. What is the red flags video?  
 24 A. It's a video that's directed to

<p style="text-align: right;">Page 589</p> <p>1 pharmacies and pharmacists, and it basically  2 talks about things that they should look for in  3 patients or individuals that are seeking to  4 divert the product.  5 Q. What is the -- what was the  6 purpose of that?  7 A. The purpose was to make sure that  8 pharmacists were aware of things to look for to  9 help to prevent diversion. We were concerned  10 about it and wanted to try to do whatever we  11 could.  12 Q. Do you know if the DEA was aware  13 of this group?  14 A. The DEA was aware of the group.  15 DEA was actually -- I believe they were sent --  16 also sent a copy of the video.  17 MR. BUCHANAN: Objection move to  18 strike, foundation.  19 BY MS. VANNI:  20 Q. You also were asked about your  21 time at -- involved in the New Jersey  22 Pharmaceutical Industry Group?  23 A. Yes.  24 Q. Do you recall that?</p>	<p style="text-align: right;">Page 591</p> <p>1 shared, but there is some detail shared.  2 Q. And why did you decide to join  3 these groups?  4 A. The group actually started, the  5 New Jersey working group actually started  6 through a request from the local DEA, and DEA  7 was looking to have a good working relationship  8 with industry and to make sure that we,  9 together, could do, you know, everything that we  10 could from a prevention of abuse and diversion.  11 MS. VANNI: At this point I don't  12 have any further questions for you. I  13 might have some follow-up after.  14 THE WITNESS: Okay.  15 MS. VANNI: Thank you. Pass the  16 witness.  17 MR. BUCHANAN: You can go off the  18 record. Thank you.  19 THE VIDEOGRAPHER: The time is  20 now 9:13. We are off the record.  21 (Brief recess.)  22 THE VIDEOGRAPHER: 9:15, back on  23 the record.  24 BY MS. KOSKI:</p>
<p style="text-align: right;">Page 590</p> <p>1 A. Mm-hmm.  2 Q. What is that?  3 A. It's a working group of peers,  4 others in the companies that handled DEA  5 compliance, and the group gets together maybe  6 once or twice a year, and the purpose is to  7 share learnings of DEA regulations and to get  8 industry to do benchmarking.  9 Q. What is benchmarking?  10 A. Basically to see what other  11 companies are doing in some areas so --  12 Q. Why is that important?  13 A. It's important because it helps  14 to -- helps to keep you abreast of what's new  15 and what's developing. It also helps to know  16 what's going on in other companies, because  17 sometimes you might want to implement something  18 internally and you're asked, you know, by others  19 in your company, well, what are other companies  20 doing? So to have that background and that  21 knowledge, to a certain extent, obviously, there  22 are, you know, pretty big confidentiality issues  23 when you're dealing with people who are our  24 competitors, so there's not a lot of detail</p>	<p style="text-align: right;">Page 592</p> <p>1 Q. Good morning, I introduced myself  2 earlier on the record, but my name is Katie  3 Koski, and I represent Anda, Inc.  4 Over the course of your  5 deposition you've been asked a lot of questions  6 or we've heard a lot of answers about a couple  7 of different concepts that I want to discuss  8 with you this morning, concepts such as ordering  9 limits or thresholds.  10 Are you familiar with that  11 concept?  12 A. Yes.  13 Q. And customer dispensing data or  14 dispensed data.  15 Do you recall talking about that?  16 A. I do.  17 Q. And we've heard reference to  18 customer questionnaires, do you recall that?  19 A. Yes.  20 Q. And there have been references to  21 electronic order monitoring or electronic order  22 systems?  23 A. Yes.  24 Q. And I'd like to ask some</p>



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1 questions about those concepts.  
2 So you've worked in DEA  
3 compliance for about 25 years; is that right?  
4 A. Yes.  
5 Q. And you understand when I refer  
6 to DEA compliance that I mean working with a  
7 company's obligations under the Federal  
8 Controlled Substances Act, right?  
9 A. I do.  
10 Q. And you're familiar with that  
11 statute?  
12 A. Yes, I am.  
13 Q. So if I referred to 21 USC  
14 Section 801, you understand what that is; is  
15 that right?  
16 A. I understand the 21 USC, yes.  
17 Q. Okay. And is it fair to say  
18 throughout the course of your career, you had  
19 occasion to review the statute?  
20 A. I have.  
21 Q. Okay. And you're familiar with  
22 Section 823 of the Act, right?  
23 A. I'm not sure exactly what 823 is  
24 but...

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1 (Document marked for  
2 identification as Par-Norton Deposition  
3 Exhibit No. 31.)  
4 BY MS. KOSKI:  
5 Q. Okay. I'm going to hand you what  
6 we've then marked as Exhibit 31.  
7 MR. BUCHANAN: You said 31?  
8 MS. KOSKI: Yes.  
9 BY MS. KOSKI:  
10 Q. And you recognize the document  
11 that I handed you as Section 823 of the  
12 Controlled Substances Act?  
13 A. Yes, I do.  
14 MR. BUCHANAN: Counsel, I just  
15 wanted to note a preliminary objection.  
16 I trust this is going to be fact  
17 testimony. It doesn't sound like it to  
18 me at this point, but I just wanted to  
19 give you notice that this does not seem  
20 to be related to the witness' experience  
21 or at least my examination of the  
22 witness, so I don't feel constrained by  
23 whatever time you use if I need more  
24 time.

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1 MS. KOSKI: We'll agree to  
2 disagree on that.  
3 MR. BUCHANAN: That's fine.  
4 BY MS. KOSKI:  
5 Q. Ms. Norton, you're familiar with  
6 the statute?  
7 A. Yes.  
8 Q. Having taken a look at it just  
9 now, Exhibit 31, does that refresh your  
10 recollection as to the statute?  
11 A. Yes, I just wasn't sure offhand  
12 what 823 was.  
13 Q. And yesterday during the course  
14 of your examination, you referred on several  
15 occasions to statutes of regulations that govern  
16 DEA compliance, the role that you served?  
17 A. Yes.  
18 Q. Okay. And if you refer to  
19 Section 823, you see that that governs the  
20 registration of pharmaceutical manufacturers and  
21 distributors, right?  
22 A. Yes, it does.  
23 Q. And we talked at length yesterday  
24 that you worked primarily for pharmaceutical

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1 manufacturers and then later in your career for  
2 a distributor; is that right?  
3 A. Yes, that's correct.  
4 Q. Okay. And for both manufacturers  
5 and distributors, Section 823 provides that the  
6 Attorney General shall register an applicant to  
7 manufacture or distribute controlled substances  
8 if he determines such registration is consistent  
9 with the public interest.  
10 Do you see that?  
11 A. Yes, I do.  
12 Q. And Section 823 in front of you  
13 also provides that "In determining the public  
14 interest, the following factors shall be  
15 considered," and then it lists several, which  
16 includes maintenance of effective controls  
17 against diversion of particular controlled  
18 substances into other than legitimate medical,  
19 scientific and industrial channels.  
20 You see that, right?  
21 A. Yes, I do.  
22 Q. In fact, that's the only section  
23 of the Controlled Substances Act that addresses  
24 maintenance of effective controls against



<p style="text-align: right;">Page 597</p> <p>1 diversion, right?</p> <p>2 MR. BUCHANAN: Objection to the</p> <p>3 form, leading, and, frankly, you should</p> <p>4 do this with experts. This is also</p> <p>5 beyond yesterday. This is not fact</p> <p>6 testimony, counsel. Put it in a legal</p> <p>7 brief, get an expert, do something, but</p> <p>8 this is not appropriate redirect</p> <p>9 examination.</p> <p>10 MS. KOSKI: You may object as to</p> <p>11 form, if you want a standing objection</p> <p>12 other than your speech that you just</p> <p>13 gave, you can have it.</p> <p>14 MR. BUCHANAN: No, I think you</p> <p>15 should know the basis of the objection.</p> <p>16 This is beyond -- this is expert.</p> <p>17 MS. KOSKI: I don't need -- I</p> <p>18 don't need to know the basis of the</p> <p>19 objection. You can object as to form.</p> <p>20 BY MS. KOSKI:</p> <p>21 Q. And I'll repeat my question.</p> <p>22 This is the only section of the</p> <p>23 Controlled Substances Act that addresses</p> <p>24 maintenance of effective controls against</p>	<p style="text-align: right;">Page 599</p> <p>1 redirect.</p> <p>2 BY MS. KOSKI:</p> <p>3 Q. The Act doesn't mention --</p> <p>4 doesn't include the phrase suspicious order,</p> <p>5 right?</p> <p>6 MR. BUCHANAN: That is leading.</p> <p>7 THE WITNESS: The CFR</p> <p>8 mentions suspicious order.</p> <p>9 BY MS. KOSKI:</p> <p>10 Q. I'm talking about the statute in</p> <p>11 front of you, the Controlled Substances Act.</p> <p>12 MR. BUCHANAN: That's leading.</p> <p>13 THE WITNESS: It does not say it</p> <p>14 here, no.</p> <p>15 BY MS. KOSKI:</p> <p>16 Q. And you know that there is no</p> <p>17 reference in the Controlled Substances Act to a</p> <p>18 "suspicious order monitoring system," correct?</p> <p>19 MR. BUCHANAN: Objection to the</p> <p>20 leading, counsel.</p> <p>21 THE WITNESS: Not to a system.</p> <p>22 BY MS. KOSKI:</p> <p>23 Q. Okay. And there's no language in</p> <p>24 the section of the Controlled Substances Act</p>
<p style="text-align: right;">Page 598</p> <p>1 diversion, right?</p> <p>2 MR. BUCHANAN: It's leading.</p> <p>3 THE WITNESS: I think overall the</p> <p>4 regulations as a whole address in</p> <p>5 different ways those controls. It does</p> <p>6 reference that specific wording here.</p> <p>7 BY MS. KOSKI:</p> <p>8 Q. Okay. And in the Controlled --</p> <p>9 the Federal Controlled Substances Act, the</p> <p>10 statute, there's no mention of suspicious order;</p> <p>11 is that fair?</p> <p>12 MR. BUCHANAN: Objection to form</p> <p>13 and the leading, counsel. It's a new</p> <p>14 area. It should be direct examination.</p> <p>15 MS. KOSKI: I'm sorry. You can</p> <p>16 object as to form, and you can preserve</p> <p>17 your record as to form.</p> <p>18 MR. BUCHANAN: You're leading a</p> <p>19 witness on expert territory, counsel.</p> <p>20 It's highly improper.</p> <p>21 MS. KOSKI: It's a form</p> <p>22 objection. You can object as to form.</p> <p>23 MR. BUCHANAN: I'll just tell</p> <p>24 you, counsel, it's not appropriate</p>	<p style="text-align: right;">Page 600</p> <p>1 that you have in front of you that says to "know</p> <p>2 your customer," right?</p> <p>3 MR. BUCHANAN: Objection to the</p> <p>4 leading, counsel.</p> <p>5 THE WITNESS: No, there is not.</p> <p>6 BY MS. KOSKI:</p> <p>7 Q. And there's no section in the</p> <p>8 Controlled Substances Act in front of you that</p> <p>9 refers to dispense data or dispensing data,</p> <p>10 right?</p> <p>11 A. There is not.</p> <p>12 MR. BUCHANAN: Objection to the</p> <p>13 leading, counsel.</p> <p>14 BY MS. KOSKI:</p> <p>15 Q. And there's no mention of</p> <p>16 customer questionnaire in the Act either, right?</p> <p>17 A. There is not.</p> <p>18 MR. BUCHANAN: Objection to the</p> <p>19 leading.</p> <p>20 You just have to give me a moment</p> <p>21 to get my objections in. Apparently,</p> <p>22 there are going to be quite a few.</p> <p>23 THE WITNESS: I'm sorry.</p> <p>24 MR. BUCHANAN: Thank you.</p>

<p style="text-align: right;">Page 601</p> <p>1 BY MS. KOSKI:</p> <p>2 Q. And the Act does not refer to</p> <p>3 internet pharmacies, right?</p> <p>4 MR. BUCHANAN: Objection to the</p> <p>5 leading.</p> <p>6 THE WITNESS: It does not.</p> <p>7 BY MS. KOSKI:</p> <p>8 Q. And there's no provision of the</p> <p>9 Act that states that distributors may not fill</p> <p>10 orders that are identified by them as</p> <p>11 potentially "suspicious orders"?</p> <p>12 MR. BUCHANAN: Objection to the</p> <p>13 leading, counsel.</p> <p>14 BY MS. KOSKI:</p> <p>15 Q. There's nothing in the Act in</p> <p>16 front of you that says that?</p> <p>17 MR. BUCHANAN: Objection to the</p> <p>18 leading. Those words, is that what</p> <p>19 you're saying?</p> <p>20 MS. KOSKI: Yes.</p> <p>21 MR. BUCHANAN: Leading.</p> <p>22 BY MS. KOSKI:</p> <p>23 Q. You can answer.</p> <p>24 A. The CFR --</p>	<p style="text-align: right;">Page 603</p> <p>1 MR. BUCHANAN: Did you serve a</p> <p>2 notice on this?</p> <p>3 MS. KOSKI: You can object as to</p> <p>4 form.</p> <p>5 MR. BUCHANAN: No, no, no, no.</p> <p>6 I'm objecting because you don't have the</p> <p>7 right to do this.</p> <p>8 If you want to do this with this</p> <p>9 witness, you need to serve a notice;</p> <p>10 otherwise, you're limited to the</p> <p>11 examination that I conducted.</p> <p>12 MS. KOSKI: And this is</p> <p>13 clearly visible --</p> <p>14 MR. BUCHANAN: This is not.</p> <p>15 MS. KOSKI: Well, we can --</p> <p>16 MR. BUCHANAN: You're using her</p> <p>17 as an expert.</p> <p>18 MS. KOSKI: This is within the</p> <p>19 scope.</p> <p>20 MR. BUCHANAN: Tender her as a</p> <p>21 26(a)(1) expert if you want to.</p> <p>22 MS. KOSKI: I'm sorry, I'm not</p> <p>23 using her as an expert.</p> <p>24 MR. BUCHANAN: Then we'll take</p>
<p style="text-align: right;">Page 602</p> <p>1 Q. Referring to the Controlled</p> <p>2 Substances Act in front of you. We'll talk</p> <p>3 about the CFR after that.</p> <p>4 A. No.</p> <p>5 Q. Okay. And the Act doesn't have</p> <p>6 any provision that requires distributors to</p> <p>7 create an ordering system that allows a customer</p> <p>8 to submit suspicious orders so that the</p> <p>9 distributor can then report those orders to the</p> <p>10 DEA, right? That's not in the language of the</p> <p>11 statute?</p> <p>12 MR. BUCHANAN: I'll object to the</p> <p>13 leading.</p> <p>14 THE WITNESS: No.</p> <p>15 MR. BUCHANAN: I'm also going to</p> <p>16 object to the examination, counsel.</p> <p>17 Did you serve a separate notice</p> <p>18 for this examination? This goes well</p> <p>19 beyond the direct examination.</p> <p>20 MS. KOSKI: It doesn't.</p> <p>21 MR. BUCHANAN: It does. Did you</p> <p>22 serve a separate notice?</p> <p>23 MS. KOSKI: If references all of</p> <p>24 the concepts that you discussed.</p>	<p style="text-align: right;">Page 604</p> <p>1 the full examination.</p> <p>2 MS. KOSKI: I'm using -- this is</p> <p>3 within the scope of your examination</p> <p>4 yesterday.</p> <p>5 MR. BUCHANAN: It's absolutely</p> <p>6 not. Does everybody here consent to</p> <p>7 this? Because if you do, it's going</p> <p>8 well beyond the time. We're going to</p> <p>9 kick open the door and we're going to go</p> <p>10 all morning.</p> <p>11 MS. KOSKI: I object to that.</p> <p>12 It's within the scope.</p> <p>13 MR. BUCHANAN: That's all right,</p> <p>14 we'll sit here.</p> <p>15 BY MS. KOSKI:</p> <p>16 Q. And you've heard reference</p> <p>17 throughout your deposition -- I think you</p> <p>18 actually referred to the term registrants,</p> <p>19 right?</p> <p>20 A. Yes.</p> <p>21 Q. Okay. And registrants are -- the</p> <p>22 term registrant is because of Section 823 that</p> <p>23 talks about the registration, right?</p> <p>24 MR. BUCHANAN: Objection to</p>

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1 foundation and the leading.  
 2 THE WITNESS: The registration.  
 3 BY MS. KOSKI:  
 4 Q. Okay. And when you referred to  
 5 the term yesterday throughout your deposition as  
 6 registrant, that was someone who was registered  
 7 to either manufacture or distribute controlled  
 8 substances pursuant to the Controlled Substances  
 9 Act; is that correct?  
 10 MR. BUCHANAN: Objection to form,  
 11 leading.  
 12 THE WITNESS: There are other  
 13 types of registration as well.  
 14 BY MS. KOSKI:  
 15 Q. And you referred during your  
 16 testimony yesterday to the DEA regulations that  
 17 relate to the distribution and manufacture of  
 18 controlled substances, right?  
 19 A. Yes.  
 20 Q. And I believe you referred to  
 21 that -- the CFR, I think you referenced that, is  
 22 that the Code of Federal Regulations?  
 23 A. Yes, it is.  
 24 Q. And is that what you were

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1 referring to when you said the DEA regulations  
 2 that you used in your work as a compliance  
 3 director?  
 4 A. Yes.  
 5 Q. Okay. And I believe you said the  
 6 regulations are -- that's what you worked with  
 7 more than the statute itself; is that right?  
 8 MR. BUCHANAN: Objection to form  
 9 and the leading.  
 10 THE WITNESS: Yes.  
 11 BY MS. KOSKI:  
 12 Q. Is that a fair summary of your  
 13 testimony yesterday that the regulations are  
 14 something you used as part of your roles and  
 15 responsibilities as a director of compliance?  
 16 MR. BUCHANAN: Objection,  
 17 overbroad.  
 18 THE WITNESS: Yes.  
 19 BY MS. KOSKI:  
 20 Q. And you know that those  
 21 regulations don't refer to "know your customer,"  
 22 right?  
 23 MR. BUCHANAN: Objection to form  
 24 and the leading.

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1 THE WITNESS: Yes.  
 2 BY MS. KOSKI:  
 3 Q. And they don't make any mention  
 4 of dispensing data?  
 5 MR. BUCHANAN: Objection to form,  
 6 leading.  
 7 THE WITNESS: They do not.  
 8 BY MS. KOSKI:  
 9 Q. And they don't refer to customer  
 10 questionnaires in the regulations, right?  
 11 MR. BUCHANAN: Objection to form,  
 12 leading.  
 13 THE WITNESS: They do not.  
 14 BY MS. KOSKI:  
 15 Q. And one of the other things that  
 16 you mentioned yesterday throughout your  
 17 testimony is guidance from DEA.  
 18 Do you recall that testimony?  
 19 A. I do.  
 20 Q. Okay. And as someone with your  
 21 background in DEA compliance, you're familiar  
 22 with the concept of guidance from the agency  
 23 that regulates your business, right?  
 24 A. Yes.

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1 Q. Okay. And guidance sort of  
 2 generally refers to the way the DEA as an agency  
 3 itself or as individual employees of the DEA  
 4 communicate with you as an industry participant;  
 5 is that a fair summary?  
 6 MR. BUCHANAN: Objection to form.  
 7 THE WITNESS: Yes.  
 8 BY MS. KOSKI:  
 9 Q. And as you talked about yesterday  
 10 and I think earlier this morning as well, it may  
 11 come in the form of a presentation given by  
 12 representatives of the agency, right?  
 13 MR. BUCHANAN: Objection to form.  
 14 THE WITNESS: Yes, that's  
 15 correct.  
 16 BY MS. KOSKI:  
 17 Q. Okay. And you've attended those  
 18 types of presentations by DEA representatives?  
 19 A. I have.  
 20 Q. Okay. Could DEA guidance also  
 21 come in the form of conversations between  
 22 representatives of the industry and members of  
 23 DEA?  
 24 MR. BUCHANAN: Objection,

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1 foundation.  
2 THE WITNESS: Yes, it could.  
3 BY MS. KOSKI:  
4 Q. In your experience, has that  
5 actually happened?  
6 A. Yes, it has.  
7 Q. And you talked a lot about that  
8 yesterday in the context of your many years in  
9 the industry; is that fair?  
10 MR. BUCHANAN: Objection,  
11 overbroad.  
12 THE WITNESS: Yes.  
13 BY MS. KOSKI:  
14 Q. Mr. Buchanan asked you about  
15 conversations you had with DEA agents?  
16 A. Yes.  
17 Q. And it may come in the form of  
18 written statements sent to one or more industry  
19 participant as well, guidance from the DEA that  
20 is?  
21 MR. BUCHANAN: Objection, form.  
22 THE WITNESS: Yes.  
23 BY MS. KOSKI:  
24 Q. And there's a -- is there a

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1 difference, in your mind, between the Controlled  
2 Substances Act that we marked as Exhibit 31 and  
3 the guidance in the form of conversations or  
4 presentations from DEA agents?  
5 MR. BUCHANAN: Objection to form.  
6 THE WITNESS: Yes, there is.  
7 BY MS. KOSKI:  
8 Q. Now, yesterday during the course  
9 of your testimony, you heard reference to things  
10 like notice of violation or I believe there was  
11 a reference to being summoned to the DEA and  
12 things like that.  
13 Do you recall that testimony?  
14 A. I do.  
15 Q. Okay. So I'd like to talk to you  
16 a little bit about your understanding of how DEA  
17 interacts with members of the industry.  
18 And so, for example, on one side  
19 of the house, DEA has some sort of, for lack of  
20 a better word, law enforcement responsibilities.  
21 Are you familiar with take?  
22 MR. BUCHANAN: Objection to form.  
23 THE WITNESS: Yes, I am.  
24 MR. BUCHANAN: I'll renew my

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1 continuing objection as to the scope of  
2 this examination.  
3 BY MS. KOSKI:  
4 Q. And by law enforcement, DEA acts  
5 as a sort of a police; is that fair?  
6 MR. BUCHANAN: Objection to form  
7 and the leading.  
8 THE WITNESS: Yes, there are  
9 agents.  
10 BY MS. KOSKI:  
11 Q. Okay. And they might investigate  
12 criminal activity, for example?  
13 A. Yes.  
14 Q. And they may refer cases to the  
15 Department of Justice for prosecution if they  
16 have reason to believe there's criminal activity  
17 happening within the industry.  
18 Are you familiar with that?  
19 A. Yes.  
20 Q. And now based on your testimony  
21 yesterday, your experience, is it fair to say,  
22 was more on the DEA's administrative or civil  
23 side of their responsibilities; is that fair?  
24 A. The meetings with DEA?

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1 Q. Right.  
2 A. Yeah.  
3 Q. Those weren't criminal in nature  
4 that you're aware of?  
5 MR. BUCHANAN: Objection to form.  
6 THE WITNESS: No, they were not.  
7 BY MS. KOSKI:  
8 Q. Okay. And over the course of  
9 your testimony yesterday, I believe we saw some  
10 documents in reference to some meetings that  
11 would have been on behalf of DEA as the agency.  
12 Do you recall that?  
13 A. I'm sorry?  
14 Q. For example, we saw a letter  
15 issued a dear registrant letter I believe that  
16 you testified about yesterday.  
17 Do you recall that testimony?  
18 A. I do.  
19 Q. Okay. And is it your  
20 understanding that was a communication sent on  
21 behalf of the agency itself?  
22 A. Yes.  
23 Q. But you've also -- you also  
24 testified yesterday, in your experience, and

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1 correct me if I'm wrong with this, that you've  
2 engaged at a more sort of one-on-one level with  
3 representatives of the agency in the course of  
4 your business, right?  
5 MR. BUCHANAN: Objection to the  
6 leading.  
7 THE WITNESS: Yes.  
8 BY MS. KOSKI:  
9 Q. And on the administrative power  
10 side, which you testified being more familiar  
11 with, you're aware that DEA can take different  
12 actions against industry participants; is that  
13 right?  
14 MR. BUCHANAN: Objection to the  
15 form.  
16 THE WITNESS: Yes.  
17 BY MS. KOSKI:  
18 Q. And you reference in some of your  
19 documents you referred to violations, I think  
20 you talked earlier about fines, possible  
21 administrative fines, right?  
22 A. Yes.  
23 Q. Okay. And as part of that,  
24 you're familiar that DEA can get a search

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1 warrant; is that right?  
2 A. Yes.  
3 Q. And they can compel a company to  
4 send individuals to appear before DEA and to  
5 testify under oath.  
6 Are you familiar with that?  
7 A. Yes.  
8 Q. And they can institute a formal  
9 proceeding like an enforcement action, right?  
10 Are you familiar with that?  
11 MR. BUCHANAN: Objection to form.  
12 This is so beyond the scope and so the  
13 subject for somebody who you're going to  
14 designate as an expert. You shouldn't  
15 be doing this in fact testimony,  
16 counsel.  
17 BY MS. KOSKI:  
18 Q. You're familiar with the roles  
19 and responsibilities of DEA over the course of  
20 your 25 years in the industry, right?  
21 A. Yes.  
22 Q. And there's also something called  
23 an order to show cause.  
24 Are you familiar with that

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1 language from the DEA?  
2 MR. BUCHANAN: Same objection.  
3 THE WITNESS: Vaguely, yes.  
4 BY MS. KOSKI:  
5 Q. All right. So with all this sort  
6 of in mind, I'd like to refer you to Exhibit 2,  
7 which I believe you have in front of you and  
8 which counsel marked yesterday. And just for  
9 purposes of folks in the room, Exhibit 2 was an  
10 e-mail cover with a copy of Ms. Hernandez, then  
11 Hernandez, sorry, resume and then also a summary  
12 of suspicious order monitoring experience.  
13 Do you recall this testimony  
14 about this document?  
15 A. I do.  
16 Q. Okay. And as I understand it,  
17 you prepared Exhibit 2, I believe you testified  
18 yesterday, in connection with applying for a  
19 job; is that right?  
20 A. Yes.  
21 Q. Okay. And the date at least on  
22 the cover e-mail is October 2014.  
23 Do you see that?  
24 A. Yes.

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1 Q. Is that around or about the time  
2 that you prepared the summary of suspicious  
3 order monitoring?  
4 A. Yes, it is.  
5 Q. Okay. And so when you prepared  
6 this, this was about -- sorry, strike that.  
7 And on the second page of the  
8 document, you see there's a reference to Watson.  
9 Do you see that?  
10 A. Yes.  
11 Q. And that's Watson Laboratories,  
12 Inc.; is that right?  
13 A. Yes.  
14 Q. And you were employed by Watson  
15 Laboratories, Inc., right?  
16 A. I was.  
17 Q. Okay. And that's reflected in  
18 Exhibit 1, your resume, if you need to look at  
19 it.  
20 A. Yes.  
21 Q. And I believe on your resume it  
22 indicates you worked at Watson from 2002 to  
23 2009; is that right?  
24 A. Yes.



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1 Q. And so this document, Exhibit 2,  
2 was prepared five years after you left Watson  
3 Laboratories; is that right?  
4 A. Yes, that's correct.  
5 Q. And I think you testified  
6 yesterday that you draft -- in the course of  
7 drafting this document, you were trying to make  
8 yourself look good to a potential employer; is  
9 that fair?  
10 MR. BUCHANAN: Objection to form.  
11 THE WITNESS: That was what was  
12 requested of me.  
13 BY MS. KOSKI:  
14 Q. And that's what you said  
15 yesterday, right?  
16 MR. BUCHANAN: Objection to form.  
17 THE WITNESS: Yes.  
18 BY MS. KOSKI:  
19 Q. All right. And I want to just  
20 look at some of the -- and I'm focused again on  
21 the Watson section and some of the things that  
22 you wrote.  
23 And you wrote that while you were  
24 employed by Watson, you did not support Anda

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1 from a DEA perspective.  
2 Do you see that?  
3 A. Yes, that's correct.  
4 Q. And that's an accurate statement,  
5 right?  
6 A. It is.  
7 Q. Okay. You never worked for Anda,  
8 Inc., right?  
9 A. I did not.  
10 Q. And you didn't work day to day in  
11 Anda's compliance department, right?  
12 A. I did not.  
13 Q. And you weren't responsible for  
14 oversight or for the actions of Anda's  
15 compliance department, right?  
16 A. I was not.  
17 Q. I believe you testified yesterday  
18 that -- and as I think you reference here, Anda  
19 had its own compliance department when it was  
20 acquired by Watson, right?  
21 A. Yes.  
22 Q. And in Exhibit 2 you describe a  
23 meeting between Anda and DEA, right?  
24 A. Yes.

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1 Q. Okay. And do you recall that the  
2 meeting was in the summer of 2007? Does that  
3 sound about right?  
4 A. I don't recall when the meeting  
5 was.  
6 Q. Fair to say that it was sometime  
7 during your employment at Watson?  
8 A. Yes.  
9 Q. And you wrote here that "Anda was  
10 summoned to DEA."  
11 Do you see that, and you spent  
12 some time on that with counsel yesterday?  
13 A. Yes.  
14 Q. Okay. And we just went through  
15 some of the ways in which the DEA exercises its  
16 criminal and administrative powers, right? Do  
17 you recall that; we just went through that?  
18 A. I do.  
19 Q. And you're familiar with that  
20 from your experience, right?  
21 A. Yes.  
22 Q. And you'll agree with me that DEA  
23 didn't issue any kind of a subpoena or some  
24 legal process to bring Anda in to appear, right?

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1 MR. BUCHANAN: Leading.  
2 THE WITNESS: They did not.  
3 MR. BUCHANAN: Objection to form.  
4 BY MS. KOSKI:  
5 Q. Did DEA issue a warrant to Anda,  
6 search warrant?  
7 A. They did not.  
8 Q. Okay. And you'll agree, won't  
9 you, that DEA didn't issue any kind of formal  
10 process like we talked about as it relates to  
11 Anda, right?  
12 MR. BUCHANAN: Objection, form,  
13 leading.  
14 THE WITNESS: No, they did not.  
15 BY MS. KOSKI:  
16 Q. And, of course, I'm focused on  
17 the time period that you were at Watson and this  
18 time period where you were dealing with this  
19 meeting with Anda.  
20 A. Understood.  
21 Q. Okay. And so to the extent here  
22 in your job application papers where you refer  
23 to summoned, you didn't mean to say that DEA  
24 issued a summons to Anda, right?

Page 621

1 A. I did not, no.  
2 Q. And as we said, Exhibit 2, that  
3 was in 2014, right?  
4 A. Yes.  
5 Q. So I want to refer you now --  
6 MR. BUCHANAN: I'm sorry,  
7 counsel, just so the record is clear,  
8 your last question was 2014, you're just  
9 referring to the date that this was  
10 prepared.  
11 BY MS. KOSKI:  
12 Q. I'm sorry, yes. The year of  
13 Exhibit 2 was 2014?  
14 A. Yes.  
15 Q. All right. And I'd like to  
16 focus, if we could, on the time period of the  
17 actual meeting that you referenced in Exhibit 2  
18 and talked a little bit about yesterday.  
19 Now, you recall that the -- you  
20 said that you weren't summoned in the formal  
21 sense, but that you -- do you recall that you  
22 received a phone call, you, Ms. Hernandez, at  
23 Watson as it related to this Anda issue with  
24 DEA?

Page 622

1 A. Yes, I did.  
2 Q. Sorry about that. My piles  
3 are -- here you go.  
4 (Document marked for  
5 identification as Par-Norton Deposition  
6 Exhibit No. 32.)  
7 BY MS. KOSKI:  
8 Q. Handing you what we marked as  
9 Exhibit 32. And for the record, this is a  
10 document with a Bates number  
11 ALLERGAN\_MDL\_03952959.  
12 And if you look on the second  
13 page of this document, this an e-mail -- just  
14 for the record, this is an e-mail that you wrote  
15 in July of 2007.  
16 Do you see that?  
17 A. Yes.  
18 Q. Okay. And on the second page, in  
19 the first full paragraph, do you see there that  
20 it says Mr. Mapes.  
21 Do you know who Mr. Mapes is?  
22 A. Yes, he was at DEA headquarters.  
23 Q. And you see the reference  
24 there -- and he worked at DEA, right?

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1 A. Yes.  
2 Q. And is it fair to say he's the  
3 person with whom you were communicating about  
4 this issue?  
5 A. Yes.  
6 Q. Do you see there's a reference it  
7 says, "Mr. Mapes also offered to meet with us to  
8 discuss the issue and internet pharmacies in  
9 general in more detail."  
10 Do you see the reference to that?  
11 A. Yes, I do.  
12 Q. And does this refresh your  
13 recollection about the circumstances under which  
14 Anda was meeting with DEA in 2007?  
15 A. Yes.  
16 Q. So, in other words, in your  
17 Exhibit -- in Exhibit 2 where you referenced  
18 Anda being summoned in, that was written in  
19 2014, right?  
20 A. Yes.  
21 Q. But at the time of your  
22 conversations in 2007 with Mr. Mapes, you make a  
23 reference here that you were -- that Mr. Mapes  
24 offered to meet with Anda, right?

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1 MR. BUCHANAN: Objection,  
2 misstates the document, form.  
3 THE WITNESS: That is what it  
4 states later in the document, yes.  
5 BY MS. KOSKI:  
6 Q. And does that refresh your  
7 recollection about what was happening in 2007?  
8 MR. BUCHANAN: Objection to form.  
9 THE WITNESS: Yes.  
10 BY MS. KOSKI:  
11 Q. And did Anda accept Mr. Mapes'  
12 invitation to meet?  
13 A. Yes.  
14 Q. Now, do you recall when after  
15 Mr. Mapes contacted you you went in to meet with  
16 him?  
17 A. I do not.  
18 Q. Was it immediate?  
19 A. I'm assuming it was close to the  
20 date, but I don't know exactly when.  
21 (Document marked for  
22 identification as Par-Norton Deposition  
23 Exhibit No. 33.)  
24 BY MS. KOSKI:

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1 Q. Handing you what we've marked as  
2 Exhibit 33. For the record, Exhibit 33 is Bates  
3 number Anda\_Opioids\_MDL\_0000152278.  
4 MR. BUCHANAN: I only have one  
5 page.  
6 MS. KOSKI: It's just a one-page  
7 document.  
8 MR. BUCHANAN: Oh, I'm sorry. I  
9 thought you were holding two, and it's  
10 Exhibit Number 33.  
11 MS. KOSKI: Thirty-three, yes.  
12 BY MS. KOSKI:  
13 Q. And you see this is an e-mail  
14 dated August 22nd, 2007?  
15 A. Yes.  
16 Q. Okay. And on the first line it  
17 says "Hello All, tomorrow's (8/23) meeting with  
18 the DEA."  
19 Do you see that?  
20 A. Yes, I do.  
21 Q. Okay. So is it fair to say the  
22 meeting was on August 23rd?  
23 A. Yes.  
24 Q. About a month after the phone

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1 call referenced in the prior exhibit?  
2 A. Yes.  
3 Q. And do you recall that the  
4 meeting was scheduled for about a two-hour time  
5 period with DEA?  
6 A. I'm not sure.  
7 Q. Do you recall it being a full day  
8 meeting?  
9 A. No, it was not.  
10 Q. And if you look at what we marked  
11 as Exhibit 33, you'll see again the first line,  
12 the meeting is scheduled from 12:00 to 2:00 p.m.  
13 Do you see that?  
14 A. Yes.  
15 Q. Is that consistent with your  
16 memory of the meeting?  
17 A. Yes.  
18 Q. Now, referring back to Exhibit 2,  
19 you wrote that DEA asked for the meeting because  
20 of Anda's, and I think I'm quoting you here,  
21 "lack of a robust SOM program."  
22 Do you recall that from the  
23 document --  
24 A. Yes.

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1 Q. -- and your testimony yesterday?  
2 Okay. Now, you had, as indicated  
3 in Exhibit 32, several calls with Mr. Mapes  
4 before the August 23rd meeting.  
5 Do you recall that?  
6 MR. BUCHANAN: Objection to form  
7 and the leading.  
8 THE WITNESS: I do not.  
9 BY MS. KOSKI:  
10 Q. Okay. If you look at Exhibit 32,  
11 you can see there's references to a number of  
12 phone calls if you read through the e-mail?  
13 A. Yes.  
14 Q. Okay. Does that refresh your  
15 recollection that you had several phone calls  
16 with Mr. Mapes before the August 23rd meeting?  
17 MR. BUCHANAN: Objection to the  
18 form and the leading.  
19 THE WITNESS: Yes.  
20 BY MS. KOSKI:  
21 Q. And the exhibit -- sorry -- 32 is  
22 a rather lengthy e-mail, Exhibit 32.  
23 Is it fair to characterize that  
24 as your notes from those phone calls, or how

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1 would you characterize what's in that e-mail?  
2 A. That is documentation of the  
3 phone calls.  
4 Q. Okay. And, again, focusing on --  
5 I think now we're on the -- if you look at the  
6 bottom of Exhibit 32, you'll see the paragraph  
7 starts on July 16, 2007.  
8 Do you see that?  
9 A. Yes.  
10 Q. It says "I received a telephone  
11 call from Michael Mapes, DEA HQ."  
12 Do you see that?  
13 A. Yes.  
14 MR. BUCHANAN: I don't, actually.  
15 Can you just highlight on Bates 60?  
16 MS. KOSKI: On page 59 and it's  
17 below the sort of the page break line,  
18 the first page of the e-mail.  
19 Do you see that, Exhibit 32?  
20 MR. BUCHANAN: Can you see it?  
21 Thank you. I got it. Thank you.  
22 BY MS. KOSKI:  
23 Q. Do you see that reference to  
24 Mr. Mapes?

<p style="text-align: right;">Page 629</p> <p>1 A. Yes.</p> <p>2 Q. And so, according to this note,</p> <p>3 you, Ms. Hernandez received a call from</p> <p>4 Mr. Mapes, right?</p> <p>5 A. Yes.</p> <p>6 Q. Okay. I believe you testified</p> <p>7 yesterday that part of the reason you were</p> <p>8 involved was because you knew the people at DEA</p> <p>9 that were involved?</p> <p>10 A. Yes.</p> <p>11 Q. Okay. And, in fact, this</p> <p>12 document indicates that the initial contact came</p> <p>13 directly to you; is that right?</p> <p>14 A. Yes, it did.</p> <p>15 Q. And if you look at the next</p> <p>16 paragraph, there's a reference there that</p> <p>17 Mr. Mapes told you DEA had seen "a steady</p> <p>18 increase in Anda sales of hydrocodone," right?</p> <p>19 That's at the bottom of the page going over to</p> <p>20 the next page.</p> <p>21 A. Yes.</p> <p>22 Q. And then you note, we don't need</p> <p>23 to read through it all, but you note a number of</p> <p>24 other things that you talked about with</p>	<p style="text-align: right;">Page 631</p> <p>1 leading.</p> <p>2 THE WITNESS: I did not have any</p> <p>3 knowledge of Anda orders at the time. I</p> <p>4 was just documenting what was told to me</p> <p>5 by Mr. Mapes.</p> <p>6 BY MS. KOSKI:</p> <p>7 Q. Okay. That's because Anda had a</p> <p>8 compliance department, right?</p> <p>9 MR. BUCHANAN: Objection to form.</p> <p>10 THE WITNESS: Yes.</p> <p>11 BY MS. KOSKI:</p> <p>12 Q. And you didn't work in it?</p> <p>13 A. Correct.</p> <p>14 Q. Okay. And then if you see in the</p> <p>15 last paragraph where you say this commitment was</p> <p>16 conveyed to Mr. Mapes by telephone on 7/16/2007.</p> <p>17 Do you see that?</p> <p>18 A. Yes.</p> <p>19 Q. So you called Mr. Mapes back</p> <p>20 after you spoke with some of the folks at Anda,</p> <p>21 right?</p> <p>22 A. Yes.</p> <p>23 Q. And that's referenced in this</p> <p>24 document, right?</p>
<p style="text-align: right;">Page 630</p> <p>1 Mr. Mapes during that initial call, right?</p> <p>2 A. Yes.</p> <p>3 Q. And then the bottom paragraph --</p> <p>4 oh, I'm sorry, in that same -- sorry, the top</p> <p>5 paragraph, you indicate that Mr. Mapes asked</p> <p>6 about the effectiveness of Anda's suspicious</p> <p>7 order monitoring program or system, excuse me.</p> <p>8 Do you see that, the top of the</p> <p>9 page marked 60?</p> <p>10 A. No, I'm sorry, I don't see where.</p> <p>11 Q. The paragraph that bleeds over</p> <p>12 from the first to the second page, and you'll</p> <p>13 see he says, "He also asked about the</p> <p>14 effectiveness of Anda's suspicious order</p> <p>15 monitoring system; quoting orders of 279,000</p> <p>16 hydrocodone dosage units sold to a single</p> <p>17 customer in a 30 day period and another for</p> <p>18 174,000."</p> <p>19 Do you see that?</p> <p>20 A. Yes, I see that.</p> <p>21 Q. And so did you understand this is</p> <p>22 in reference to two specific orders that Anda</p> <p>23 had filled?</p> <p>24 MR. BUCHANAN: Objection to the</p>	<p style="text-align: right;">Page 632</p> <p>1 A. Mm-hmm, yes.</p> <p>2 (Document marked for</p> <p>3 identification as Par-Norton Deposition</p> <p>4 Exhibit No. 34.)</p> <p>5 BY MS. KOSKI:</p> <p>6 Q. Handing you what we marked as</p> <p>7 Exhibit 34.</p> <p>8 MS. KOSKI: Counsel. And for the</p> <p>9 record, Exhibit 34 is Bates</p> <p>10 Anda_Opioids_MDL_0000275627.</p> <p>11 BY MS. KOSKI:</p> <p>12 Q. Do you see that?</p> <p>13 A. Yes.</p> <p>14 Q. Okay. And what's this document?</p> <p>15 A. It's an internal e-mail from</p> <p>16 myself to Diane Miranda and Al Paonessa.</p> <p>17 Q. With a CC to Michael Cochrane and</p> <p>18 Patrick Cochrane?</p> <p>19 A. Yes.</p> <p>20 Q. And what's the date on it?</p> <p>21 A. July 31st, 2007.</p> <p>22 Q. Okay. And the subject is "DEA</p> <p>23 Teleconference re: CS Distribution/Anda."</p> <p>24 Do you see that?</p>

<p style="text-align: right;">Page 633</p> <p>1 A. Yes.</p> <p>2 Q. Okay. And is it -- and the first</p> <p>3 reference there is "today we finally got to have</p> <p>4 our teleconference with DEA."</p> <p>5 Do you see that?</p> <p>6 A. Yes.</p> <p>7 Q. So the today referenced there</p> <p>8 would be the date of the e-mail; is that fair?</p> <p>9 A. Yes.</p> <p>10 Q. Okay. So this is, in fact, a</p> <p>11 third call you had with DEA relating to the Anda</p> <p>12 issues?</p> <p>13 A. It is another call, yes.</p> <p>14 Q. Okay. And you made notes of that</p> <p>15 call as well, right?</p> <p>16 A. Yes.</p> <p>17 Q. And that's reflected in what we</p> <p>18 just marked as Exhibit 34?</p> <p>19 A. Yes.</p> <p>20 Q. And these notes were made the</p> <p>21 same day as the phone call, right?</p> <p>22 A. Yes.</p> <p>23 Q. Fair to say it would have been</p> <p>24 fresh in your memory at the time that you wrote</p>	<p style="text-align: right;">Page 635</p> <p>1 interaction you indicated that after or during</p> <p>2 your discussions with DEA, Anda made some</p> <p>3 changes to its SOMS program, right?</p> <p>4 A. Yes.</p> <p>5 Q. Okay. And I think you referred</p> <p>6 to a limit, but I don't know that you put a</p> <p>7 number on it.</p> <p>8 A. Yes.</p> <p>9 Q. Okay. Does this refresh your</p> <p>10 recollection about the number?</p> <p>11 A. It does.</p> <p>12 Q. Okay. And you also discuss other</p> <p>13 things or you reflect your discussion with</p> <p>14 Mr. Mapes about other things as well here in</p> <p>15 Exhibit 34, and you discussed two customers in</p> <p>16 particular who had -- whose legitimate needs</p> <p>17 dictate quantities greater than 5,000 a month.</p> <p>18 Do you see that?</p> <p>19 A. Yes, I do.</p> <p>20 Q. And that's a reflection of the</p> <p>21 discussion that Anda had with Mr. Mapes on</p> <p>22 July 31st of 2007?</p> <p>23 A. Yes.</p> <p>24 Q. And then you say here, "His exact</p>
<p style="text-align: right;">Page 634</p> <p>1 the e-mail?</p> <p>2 A. Yes.</p> <p>3 Q. And as reflected in this e-mail,</p> <p>4 you discussed Anda's decision to establish new</p> <p>5 limits on customers who purchase controlled</p> <p>6 substances from Anda, right, beginning of the</p> <p>7 second paragraph. You need reference?</p> <p>8 A. Yes, it talks about limits.</p> <p>9 Q. Right, and that's Anda's decision</p> <p>10 to establish the new limits, right?</p> <p>11 MR. BUCHANAN: Objection to form.</p> <p>12 BY MS. KOSKI:</p> <p>13 Q. We're talking about Anda here?</p> <p>14 A. Yes.</p> <p>15 Q. And the new limit was 5,000</p> <p>16 dosage units per drug family.</p> <p>17 Do you see that?</p> <p>18 A. For hydrocodone products, yes.</p> <p>19 Q. And other controlled substances</p> <p>20 with a high diversion potential.</p> <p>21 Do you see that?</p> <p>22 A. Yes.</p> <p>23 Q. Okay. And yesterday you referred</p> <p>24 to and you were talking about your -- this</p>	<p style="text-align: right;">Page 636</p> <p>1 words were that '5,000 dosage units is not a</p> <p>2 hard limit, but a start' and that as long as we</p> <p>3 are making the effort to know the customer's</p> <p>4 business he is fine with that."</p> <p>5 Do you see that reference?</p> <p>6 A. I do.</p> <p>7 Q. And that's reflecting your</p> <p>8 conversation at the time with Mr. Mapes, right?</p> <p>9 A. Yes.</p> <p>10 Q. And if you refer back to I</p> <p>11 believe it's Exhibit 32 or in your first call,</p> <p>12 you indicate that Mr. Mapes had expressly</p> <p>13 referred to some specific large orders as the</p> <p>14 reason -- one of the reasons, at least, for the</p> <p>15 phone call that he made to you, right?</p> <p>16 A. Yes.</p> <p>17 Q. And so here on July 31st, you're</p> <p>18 discussing -- you reflect -- you're reflecting</p> <p>19 your discussion with Mr. Mapes where you talked</p> <p>20 about that, the large order situation, fair?</p> <p>21 MR. BUCHANAN: Object to the</p> <p>22 leading.</p> <p>23 THE WITNESS: Without knowing the</p> <p>24 customers, I'm not sure if that's the</p>



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<p>1 same, but there is -- there are comments</p> <p>2 here, yes.</p> <p>3 BY MS. KOSKI:</p> <p>4 Q. And the idea being that for some</p> <p>5 specific customers, dispensing more than the</p> <p>6 5,000 per month that was recommended by DEA</p> <p>7 could be appropriate, right?</p> <p>8 MR. BUCHANAN: Objection to the</p> <p>9 form.</p> <p>10 THE WITNESS: Yes.</p> <p>11 BY MS. KOSKI:</p> <p>12 Q. And that's reflected in your</p> <p>13 notes that you wrote at the time, right?</p> <p>14 MR. BUCHANAN: Objection to the</p> <p>15 form.</p> <p>16 THE WITNESS: Yes, that's based</p> <p>17 on the comments from DEA.</p> <p>18 BY MS. KOSKI:</p> <p>19 Q. If you look back to 32, and this</p> <p>20 was the e-mail we were just looking at that</p> <p>21 referred to the initial phone call you received</p> <p>22 from Mr. Mapes, right?</p> <p>23 A. Yes.</p> <p>24 Q. And if you see on the second page</p>	<p>1 to the actions taken against Southwood,</p> <p>2 Bellco, Richie, those companies?</p> <p>3 BY MS. KOSKI:</p> <p>4 Q. Right, right.</p> <p>5 A. Yes.</p> <p>6 Q. So you refer -- you refer here in</p> <p>7 your notes to recent regulatory actions DEA has</p> <p>8 taken, right?</p> <p>9 A. Yes.</p> <p>10 Q. And we talked earlier this</p> <p>11 morning about some of the types of regulatory</p> <p>12 actions that DEA is empowered to take, right?</p> <p>13 A. Yes.</p> <p>14 Q. And did you understand that's</p> <p>15 what Mr. Mapes was referring to with respect to</p> <p>16 these other companies?</p> <p>17 MR. BUCHANAN: Objection to form.</p> <p>18 THE WITNESS: Yes.</p> <p>19 BY MS. KOSKI:</p> <p>20 Q. Now, DEA never instituted any</p> <p>21 formal action against Anda while you worked at</p> <p>22 Anda, right?</p> <p>23 MR. BUCHANAN: Objection to form.</p> <p>24 MS. KOSKI: Excuse me. Strike</p>
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<p>1 of the document, there's a reference in your</p> <p>2 notes about what -- that Mr. Mapes, I believe is</p> <p>3 the he, referenced recent regulatory actions DEA</p> <p>4 has taken against, and he names some entities,</p> <p>5 not Anda, right?</p> <p>6 A. Yes.</p> <p>7 Q. Okay. And you recorded that in</p> <p>8 these notes from your conversation with him at</p> <p>9 the time?</p> <p>10 A. I did.</p> <p>11 Q. Now, when we talked earlier about</p> <p>12 DEA has different mechanisms of communicating</p> <p>13 with the industry, DEA has different formal</p> <p>14 processes they could take, did you understand</p> <p>15 that was what Mr. Mapes was referencing here in</p> <p>16 this document?</p> <p>17 MR. BUCHANAN: Objection to the</p> <p>18 form. Which document are you</p> <p>19 referencing, counsel?</p> <p>20 MS. KOSKI: Exhibit 32 that you</p> <p>21 have in your hand.</p> <p>22 MR. BUCHANAN: Objection to form,</p> <p>23 vague.</p> <p>24 THE WITNESS: Are you referring</p>	<p>1 that.</p> <p>2 BY MS. KOSKI:</p> <p>3 Q. DEA never instituted any formal</p> <p>4 action against Anda while you worked at Watson,</p> <p>5 right?</p> <p>6 A. Not that I'm aware of.</p> <p>7 Q. Instead, you -- this experience</p> <p>8 that you had with Mr. Mapes was a series of</p> <p>9 telephone calls and an agreed meeting; is that</p> <p>10 fair?</p> <p>11 A. Yes.</p> <p>12 Q. And I believe you discussed</p> <p>13 yesterday and maybe earlier this morning the</p> <p>14 distributor initiative that you believe this</p> <p>15 related to?</p> <p>16 MR. BUCHANAN: Objection to form</p> <p>17 and the leading.</p> <p>18 THE WITNESS: Yes.</p> <p>19 BY MS. KOSKI:</p> <p>20 Q. And, in fact, during your</p> <p>21 conversations, you had an exchange of</p> <p>22 information with Mr. Mapes; is that fair?</p> <p>23 A. Yes.</p> <p>24 Q. And when we talked earlier about</p>

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1 guidance received from DEA, would this fall into  
2 what you've referred to over the course of the  
3 couple days as guidance?  
4 A. Yes.  
5 Q. And, in fact, outside of this  
6 narrow context with Anda, you've had other  
7 occasions to have conversations with DEA, right?  
8 A. Yes.  
9 Q. And then just looking back at  
10 Exhibit 2 quickly, which is your employment  
11 application, for lack of a better word, do you  
12 have that Exhibit 2, the e-mail with your  
13 resume? Of course, it's at the bottom of the  
14 pile. It's at the bottom of the pile.  
15 A. Yes.  
16 Q. And do you see in there that you  
17 wrote that the meeting was for cause?  
18 A. Yes.  
19 Q. And when we talked about DEA has  
20 formal actions, we talked at one point about  
21 orders to show cause. That's one of the formal  
22 processes, right?  
23 A. It is, yes.  
24 Q. And an order to show cause is

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1 something that actually compels the registrant  
2 to appear before DEA, right?  
3 A. Yes.  
4 Q. Okay. And you didn't mean to  
5 suggest in Exhibit 2, in your employment  
6 application documents, that DEA issued an order  
7 to show cause to Anda, right?  
8 A. They did not.  
9 Q. In fact, they didn't do that,  
10 right?  
11 A. Correct.  
12 Q. And as long as you worked at  
13 Watson, you weren't aware of any occasion in  
14 which DEA issued Anda an order to show cause,  
15 right?  
16 A. I'm not aware of any.  
17 MR. BUCHANAN: Objection to the  
18 leading, move to strike.  
19 BY MS. KOSKI:  
20 Q. And, again, as we've gone through  
21 your contemporaneous notes from August of 2007,  
22 when the meeting happened, the meeting was a  
23 result of some exchanges between Anda and DEA  
24 and an invitation from you, right?

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1 MR. BUCHANAN: Objection to form,  
2 misstates the evidence.  
3 THE WITNESS: Yes.  
4 MS. KOSKI: That's all I have.  
5 Thank you.  
6 THE WITNESS: Thank you.  
7 MR. BUCHANAN: Do any other  
8 defense counsel have questions? We can  
9 close the record -- close it on that. I  
10 have follow-up questions. Go off the  
11 record for a few minutes.  
12 THE VIDEOGRAPHER: The time is  
13 9:57. Off the record.  
14 (Brief recess.)  
15 THE VIDEOGRAPHER: The time is  
16 10:24 a.m. This begins DVD Number 2.  
17 We are back on the record.  
18 BY MR. BUCHANAN:  
19 Q. Ms. Norton, I have a few  
20 questions in follow-up to the questions asked by  
21 Endo's counsel, Qualitest's counsel as well as  
22 Anda counsel.  
23 A. Yes.  
24 Q. Before I do that, though, can we

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1 agree that you and I hadn't met before today?  
2 A. We met yesterday.  
3 Q. That's fair. Before your  
4 deposition began, we can agree on that?  
5 A. Yes.  
6 Q. Thank you. Obviously, you told  
7 us that you had an opportunity to meet with  
8 counsel for Endo, I think, before your testimony  
9 yesterday, correct?  
10 A. Yes.  
11 Q. Three days?  
12 A. Yes.  
13 Q. Multiple hours each time?  
14 A. Yes.  
15 Q. Did you have an opportunity to  
16 meet with Anda's counsel before you answered  
17 questions today?  
18 A. Briefly by phone.  
19 Q. And in that regard, did you  
20 review or discuss documents to refresh your  
21 recollection?  
22 A. Yes.  
23 Q. Okay. And what were they?  
24 MS. KOSKI: Objection.

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1 MS. LEIBELL: Objection.  
2 BY MR. BUCHANAN:  
3 Q. Did they refresh your  
4 recollection?  
5 A. Yes.  
6 Q. What were they?  
7 A. The Mike Mapes' phone call,  
8 documentation of the first phone call.  
9 Q. Okay. So you worked through that  
10 document?  
11 A. The first one, yes.  
12 Q. Before you came in today?  
13 A. Yes.  
14 Q. Did you do that again before you  
15 testified this morning?  
16 A. No.  
17 Q. Okay. Any other documents that  
18 refreshed your recollection?  
19 A. No.  
20 Q. Okay. I'd like now to start, and  
21 we'll get to the Anda portion of this. I'd like  
22 to start with your testimony relating to your  
23 time at Qualitest.  
24 You joined in 2011, you left in

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1 2014, right?  
2 A. Yes.  
3 Q. You were asked some general  
4 questions, I think open-ended questions about  
5 describe your SOM process.  
6 Do you recall those questions on  
7 examination by Endo counsel?  
8 A. Yes.  
9 Q. Okay. And you gave a list of  
10 things that were done. You would look at order  
11 of interests. You would look at the customer's  
12 specific history, look at the customer  
13 questionnaire. You would get customer feedback.  
14 You would go and visit customers. You would do  
15 that whole process.  
16 Do you recall that?  
17 A. Yes.  
18 Q. That process was implemented, if  
19 I understand your testimony correctly, in 2013?  
20 A. Over time.  
21 Q. The process you described with  
22 those items that I just listed, that was the  
23 process in place as of 2013, correct?  
24 A. It was, yes.

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1 Q. Also incorporated at some point  
2 in time after 2013, consideration of IMS data,  
3 correct?  
4 A. I don't know the exact date as to  
5 when it was implemented. That was before -- I  
6 don't know exact date, but 2013, yes.  
7 Q. Yeah, we looked at documents in  
8 early 2013 where you said we need to start  
9 incorporating IMS data.  
10 Do you recall that?  
11 A. Yes.  
12 Q. So you hadn't been doing it prior  
13 to 2013, correct?  
14 MS. VANNI: Object to form.  
15 THE WITNESS: We had IMS data.  
16 This was different data.  
17 BY MR. BUCHANAN:  
18 Q. Yeah, I'm referring to IMS data  
19 so that you could evaluate your customer  
20 thresholds or customer levels to see whether  
21 they were buying above or below national  
22 averages for classes of trade?  
23 A. Yes, correct.  
24 Q. You were not doing that prior to

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1 2013, correct?  
2 A. No.  
3 Q. I'm correct?  
4 A. Yes, you are correct.  
5 Q. Thank you. We talked yesterday  
6 about the incorporation of chargeback data into  
7 the process and looked at some correspondence  
8 where Mr. Brantley was using chargeback data in  
9 connection with his correspondence with your  
10 direct customers to talk about issues with  
11 customers of customers.  
12 Do you recall that?  
13 A. Yes, I do.  
14 Q. Use of chargeback data was not  
15 being done prior to 2013, correct?  
16 A. Correct.  
17 Q. And we looked at documents  
18 yesterday where, in your own words, you said you  
19 needed to revamp the SOM process in 2013,  
20 correct?  
21 A. Yes.  
22 Q. And we further looked at  
23 documents yesterday where you were told in 2013  
24 that your current SOM program systems and

<p style="text-align: right;">Page 649</p> <p>1 procedures do not meet the regulatory 2 requirements. 3 Do you recall that? 4 MS. VANNI: Object to form. 5 THE WITNESS: I'm not sure what 6 document it was. 7 BY MR. BUCHANAN: 8 Q. E-15, I'm sorry, Exhibit 15, it's 9 E1052. Can we go to 1052.1. I don't have the 10 exhibits to give you. There's a stack right 11 there. 12 All right. Let's -- we see this 13 correspondence between yourself and Ms. Connell, 14 your boss at the time? 15 A. Yes, correct. 16 Q. Okay. It says, "Jill, I added 17 the action items and the estimated completion. 18 If Judy can put them in the Gantt chart it would 19 be a big help. Again, the dates are estimates 20 since input is needed from other departments to 21 confirm." 22 This is an e-mail from yourself 23 to your boss in 2013, again before you sat down 24 with DEA, correct?</p>	<p style="text-align: right;">Page 651</p> <p>1 the consultant opinion, we can look at yours as 2 of the same time. Exhibit 16, could we please 3 go to E.1071. 4 And here we have, ma'am, a 5 presentation you put together for Ms. Connell 6 around the same period of time, February 2013. 7 Do you see that? 8 A. Yes. 9 Q. I'm on the cover letter right 10 now. 11 A. Yes. 12 Q. Okay. And you were putting 13 together action items and things that needed to 14 be done and to address various compliance issues 15 you were having at that time, correct? 16 MS. VANNI: Object to form. 17 THE WITNESS: Improvements that 18 we wanted to make, not compliance 19 issues. 20 BY MR. BUCHANAN: 21 Q. Let's go to 1071.8. 22 We can agree at this point in 23 time, ma'am, with regard to your SOM program, 24 you identified it as inadequate, correct?</p>
<p style="text-align: right;">Page 650</p> <p>1 A. Correct. 2 Q. Some consultants had come in and 3 looked at your systems, spent a couple days on 4 site looking at things, correct? 5 A. Yes. 6 Q. All right. Could we go to .3. 7 And the consultants concluded, 8 can we highlight that paragraph, there you go. 9 "The consultants concluded that our current SOM 10 program, systems and procedures" -- could you 11 read the rest? 12 A. "Do not meet the regulatory 13 requirements." 14 Q. Thank you. 15 In fact, this was before the DEA 16 had to tell you that, right? 17 MS. VANNI: Object to form. 18 THE WITNESS: This was the 19 consultant's opinion that was given 20 before we met with DEA, yes. 21 BY MR. BUCHANAN: 22 Q. Fair enough. Could you look at 23 Exhibit 16, ma'am. 24 And we don't have to just look at</p>	<p style="text-align: right;">Page 652</p> <p>1 A. That is what I wrote, yes. 2 Q. Right. Inadequate as in not 3 adequate, correct? 4 MS. VANNI: Object to form. 5 THE WITNESS: Inadequate as in 6 not meeting the -- my goals, not meeting 7 my goals for the program. 8 BY MR. BUCHANAN: 9 Q. And what you wrote here was 10 "Inadequate SOMS," correct? 11 A. That is what's written. 12 Q. And what you wrote in other 13 documents and one of which was shown to you this 14 morning by defense counsel was that you had a 25 15 risk assessment to your SOM program at the same 16 point in time, correct? 17 MS. VANNI: Object to form. 18 THE WITNESS: Yes, based on 19 improvements I wanted to make. 20 MR. BUCHANAN: And move to strike 21 the nonresponsive portion. 22 BY MR. BUCHANAN: 23 Q. And the weakness, you have many 24 weaknesses that are listed here with regard to</p>

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1 SOMS, you note inadequate SOMS, correct?  
2 MS. VANNI: Object to colloquy.  
3 THE WITNESS: That is what it  
4 says.  
5 BY MR. BUCHANAN:  
6 Q. With regard to resources, you say  
7 "Limited Resources," correct?  
8 A. Yes, we were waiting to hire  
9 additional people.  
10 Q. Okay. Well, to be clear, I think  
11 in talking about your DEA compliance group on  
12 direct examination with defense counsel, you  
13 said that when you got to the company -- how  
14 many people were in DEA compliance?  
15 A. One.  
16 Q. One, okay.  
17 And pause on that for a moment.  
18 Can you pull up Exhibit 4, and for the video --  
19 excuse me for the display screens, it's E1157.1.  
20 As of 2011 -- was your testimony  
21 yesterday that 70% of the company's business was  
22 controlled substances, ma'am?  
23 A. I said approximately. I didn't  
24 know exact.

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1 Q. Okay. As of 2011 we see -- what  
2 is that, over 2 billion controlled substances?  
3 A. Again, I can't speak to the  
4 detail of this document. I don't know what went  
5 into it.  
6 Q. Okay. We could agree the company  
7 made a lot of controlled substances, right?  
8 MS. VANNI: Object to form.  
9 THE WITNESS: They were in the  
10 controlled substance business.  
11 BY MR. BUCHANAN:  
12 Q. Right, and as a company in the  
13 controlled substance business, they had one  
14 person in DEA compliance; is that right?  
15 MS. VANNI: Object to form.  
16 THE WITNESS: At the time, yes.  
17 BY MR. BUCHANAN:  
18 Q. When you were hired as of 2011.  
19 MR. BUCHANAN: Can you take that  
20 down. Can you blow out 2008 through  
21 2011 with the legend on the left with  
22 drugs and years.  
23 BY MR. BUCHANAN:  
24 Q. And so for 2011, when you joined,

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1 and for the years prior, we could agree the  
2 company was making billions and billions and  
3 billions of controlled substances that were  
4 entering the market, correct?  
5 MS. VANNI: Object to the form.  
6 THE WITNESS: Again, I can't  
7 speak to the data or to things that  
8 happened before I arrived.  
9 MR. BUCHANAN: Okay. I mean,  
10 this is a bit of a challenge because  
11 defense counsel has pointed us to what  
12 I'm now going to mark as Exhibit 35.  
13 Is that correct, 35 is next in  
14 order?  
15 (Document marked for  
16 identification as Par-Norton Deposition  
17 Exhibit No. 35.)  
18 BY MR. BUCHANAN:  
19 Q. Passing you, ma'am, Exhibit 35.  
20 There you go. And I'll represent to you, ma'am,  
21 that the summary table that was presented to you  
22 was derived from these spreadsheets that defense  
23 counsel provided to us.  
24 I guess what I'd like to -- what

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1 I'd like to understand, ma'am, is in 2008 how  
2 many hydrocodone APAP did Qualitest ship?  
3 A. Again, I don't know where this  
4 data came from. I don't know how it was pulled  
5 for research, and I wasn't here in 2008 to speak  
6 to it.  
7 Q. I take it you're familiar with  
8 this type of form, correct?  
9 A. I am not familiar with this type  
10 of form.  
11 Q. Okay. As the head of DEA  
12 compliance, did you review data on the quantity  
13 of pills the company was shipping?  
14 A. We had to do reports that gave  
15 accountability of what we were shipping, yes.  
16 Q. Did you get them in a more user  
17 friendly form than this?  
18 MS. VANNI: Object to form.  
19 THE WITNESS: Yes.  
20 BY MR. BUCHANAN:  
21 Q. You did?  
22 A. Well, some of it, sometimes.  
23 Q. You could get your data and  
24 systems team to identify for you the quantity of



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1 shipped material?  
2 A. Not all. Different things were  
3 in different systems.  
4 Q. If you wanted to get the quantity  
5 of sales to customers could you get that, ma'am?  
6 A. Depends on what is called sales.  
7 So are -- if we're referring to direct shipment  
8 to customer, we could get some information, yes,  
9 more information after SAP was implemented, but  
10 not at first.  
11 Q. I assume the company kept track  
12 of the drugs that it was selling to its  
13 customers?  
14 A. Yes.  
15 Q. Okay. Company had systems to do  
16 that?  
17 A. Systems and electronic -- some  
18 electronic, some manual.  
19 Q. And we've had computers for a  
20 long time, right?  
21 A. Yes, we have.  
22 Q. Okay. So as of matter of  
23 processing large volumes of orders, the company  
24 had a computer system, correct?

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1 A. For some things, yes.  
2 Q. For keeping track of shipments to  
3 customers, correct?  
4 A. Parts of that data, yes.  
5 Q. And keeping track of orders to  
6 customers, correct?  
7 A. Parts of that data, yes.  
8 Q. Right. Well, just if you could,  
9 ma'am, just look through this and please tell us  
10 the volume of hydrocodone APAP product that was  
11 shipped in your first year, 2011?  
12 MR. BUCHANAN: I'm sorry, please  
13 take that document down.  
14 MS. VANNI: Counsel, if you  
15 wouldn't mind, could you read the Bates  
16 number in. I saw it and now it sort of  
17 disappeared, and I don't know where it  
18 went.  
19 MR. BUCHANAN: You know what, I  
20 gave you a copy. I'll give you another  
21 one to take home. My paralegal does  
22 have an extra copy. I wasn't sure  
23 whether this was an appropriate one for  
24 broader distribution, so I'm giving it

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1 with the witness.  
2 MS. VANNI: I appreciate that  
3 because it is marked highly  
4 confidential.  
5 MR. BUCHANAN: It's from the  
6 witness' time at the company, so I  
7 believe it's an appropriate use, but I'm  
8 being sensitive to whatever concerns you  
9 may have on its distribution. You can  
10 address that with your co-counsel --  
11 co-defense counsel at a later point in  
12 time. I am not burning it into the  
13 video feed.  
14 BY MR. BUCHANAN:  
15 Q. Looking through it, ma'am, could  
16 you please, what I've identified as Exhibit --  
17 was that 38 -- 35, could you tell us, please,  
18 the shipments for hydrocodone products in 2011?  
19 A. I'm sorry, I can't read it. It's  
20 very small.  
21 Q. I'll give you some time to see if  
22 you can sum that up or give us a number.  
23 A. I don't see a total. I see line  
24 items.

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1 Q. How about for oxycodone shipments  
2 in 2011, ma'am?  
3 A. I don't see totals on here. I  
4 just see line items, individual line items.  
5 Q. Would my question be easier to  
6 answer if I said orders?  
7 A. No, it would not.  
8 Q. How about orders of hydrocodone,  
9 orders of oxycodone, the quantities that you  
10 received in 2011?  
11 A. No. I mean, this is -- these are  
12 individual customer orders, by the looks of it.  
13 I don't know when they occurred, since I can't  
14 see the dates.  
15 Q. I just need the totals, ma'am.  
16 A. I can't. There's no -- I don't  
17 know where the totals are in here.  
18 Q. There was some question about the  
19 providence of the exhibit that we prepared and  
20 showed to you and you had questions about where  
21 things came from. I provided that to you.  
22 So my question now is can you  
23 give us the shipments of hydrocodone and  
24 oxycodone for the years that we're talking

<p style="text-align: right;">Page 661</p> <p>1 about?</p> <p>2 A. I cannot. What you provided me</p> <p>3 is a report that I can't read that I would need</p> <p>4 a considerable amount of time to go through in</p> <p>5 order to pull information out of, and I don't</p> <p>6 even know if it contains transfers or just</p> <p>7 financial transactions or what it contains, so I</p> <p>8 can't on the spot give you that information.</p> <p>9 Q. All great questions of the data.</p> <p>10 MR. BUCHANAN: Counsel, we'll</p> <p>11 take your stipulations as to all those</p> <p>12 numbers if you'll provide them kindly.</p> <p>13 Do you have them?</p> <p>14 MS. VANNI: Do I have what? Do I</p> <p>15 have the --</p> <p>16 MR. BUCHANAN: The information in</p> <p>17 the numbers the witness is asking for,</p> <p>18 because this is where you pointed us --</p> <p>19 I mean, I'm not comfortable with the</p> <p>20 witness questioning the providence of</p> <p>21 the data you've shown -- told us to go</p> <p>22 to look at, so I'll take your</p> <p>23 representations and stipulations as to</p> <p>24 what it is.</p>	<p style="text-align: right;">Page 663</p> <p>1 making a lot of hydrocodone and a lot of</p> <p>2 oxycodone in 2011 when you got to the company,</p> <p>3 right?</p> <p>4 MS. VANNI: Object to form.</p> <p>5 THE WITNESS: The company was</p> <p>6 making hydrocodone and oxycodone. I</p> <p>7 don't want to define a lot. I don't</p> <p>8 know what we're comparing it to. It's</p> <p>9 been...</p> <p>10 BY MR. BUCHANAN:</p> <p>11 Q. Okay. Well, I'll ask you to stay</p> <p>12 with me on this, and I'll ask you to assume that</p> <p>13 the company was making billions of pills of</p> <p>14 oxycodone or hydrocodone per year. Is that a</p> <p>15 lot to you?</p> <p>16 MS. VANNI: Object to form.</p> <p>17 THE WITNESS: That's opinion.</p> <p>18 BY MR. BUCHANAN:</p> <p>19 Q. Okay. You gave opinions</p> <p>20 throughout the day.</p> <p>21 A. I have nothing to compare it to.</p> <p>22 I can't comment on what "a lot" is.</p> <p>23 Q. You don't have an opinion as to</p> <p>24 whether billions of hydrocodone pills, hundreds</p>
<p style="text-align: right;">Page 662</p> <p>1 MS. VANNI: I can't stipulate to</p> <p>2 anything. This was a document that I'm</p> <p>3 seeing for the first time today that</p> <p>4 you've presented to me in an illegible</p> <p>5 form. I don't know if this was prepared</p> <p>6 for purposes of litigation. I don't</p> <p>7 know what this document is. I</p> <p>8 apologize, but I can't stipulate to</p> <p>9 anything because I don't even know what</p> <p>10 it is. I can't even read it.</p> <p>11 MR. BUCHANAN: All good points</p> <p>12 you're raising, and I don't think it's</p> <p>13 any different in reverse on this side of</p> <p>14 the base, certainly, because we don't</p> <p>15 have the resources to confirm any of</p> <p>16 that information, but this is the</p> <p>17 spreadsheet you called to our attention</p> <p>18 as 33C in your rog responses.</p> <p>19 Okay. I'll move on at this</p> <p>20 point.</p> <p>21 BY MR. BUCHANAN:</p> <p>22 Q. Ma'am, we were looking at 1071.8.</p> <p>23 We can agree, even though we can't pin down the</p> <p>24 actual numbers of pills, that the company was</p>	<p style="text-align: right;">Page 664</p> <p>1 of millions of oxycodone pills is a lot?</p> <p>2 A. No, I don't.</p> <p>3 MS. VANNI: Objection, asked and</p> <p>4 answered and argumentative.</p> <p>5 BY MR. BUCHANAN:</p> <p>6 Q. As the head of DEA compliance who</p> <p>7 was the person in charge of ensuring the</p> <p>8 adequacy of the company's SOMS system --</p> <p>9 A. Yes.</p> <p>10 Q. -- you don't have an opinion as</p> <p>11 to whether the company was making a lot --</p> <p>12 MS. VANNI: Objection.</p> <p>13 BY MR. BUCHANAN:</p> <p>14 Q. -- of oxycodone or hydrocodone?</p> <p>15 A. No, I don't have comparisons to</p> <p>16 other companies. I don't have -- no, I don't</p> <p>17 have an opinion.</p> <p>18 Q. Okay. Let's come back now to</p> <p>19 weaknesses of the company as of this 2013</p> <p>20 document. You had weaknesses related to DEA</p> <p>21 security and controls, right?</p> <p>22 A. Things I wanted to improve upon,</p> <p>23 yes.</p> <p>24 Q. What you wrote was weaknesses?</p>

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1 A. That's what the document says.  
2 Q. Right, and you wrote "Weaknesses,  
3 DEA related Security and Controls," item one,  
4 correct?  
5 A. Yes.  
6 Q. In this company where 70% of its  
7 business was controlled substances, correct?  
8 MS. VANNI: Object to form.  
9 THE WITNESS: Yes.  
10 BY MR. BUCHANAN:  
11 Q. You had weaknesses regarding  
12 "Lack of Data Visibility, Processes & Systems,"  
13 correct?  
14 A. Again, things I wanted to  
15 improve.  
16 Q. You had weaknesses in terms of  
17 limited resources, one head count for DEA  
18 compliance during the time -- at the time you  
19 started with the company, correct?  
20 A. Because functions were being  
21 handled by other groups as well.  
22 Q. Not because. You had limited  
23 resources and that was a weakness as of 2013,  
24 not even 2011, correct?

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1 A. I had limited people --  
2 MS. VANNI: Object to form.  
3 THE WITNESS: -- in my  
4 department. That doesn't mean that  
5 regulations were not being followed.  
6 BY MR. BUCHANAN:  
7 Q. Just stay with my question,  
8 ma'am.  
9 What you wrote was that you had  
10 limited resources, and that was a weakness,  
11 agreed?  
12 A. That's what's written.  
13 Q. Thank you. Another weakness was  
14 a "Lack of Training & Compliance first culture."  
15 Did I read that correctly?  
16 A. You did.  
17 Q. You had the weakness of  
18 "Inadequate SOMS" that we've talked about,  
19 correct?  
20 A. That's what it says.  
21 Q. And you had "Day-to-day  
22 challenges and the depth of compliance  
23 activities are not visible to the organization,"  
24 correct?

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1 A. Yes, that's what the document  
2 reads.  
3 Q. Okay. And so then you talked  
4 about this meeting you had with DEA in March of  
5 2013, and you characterized it for us yesterday,  
6 perhaps recharacterized it today, but fair to  
7 say throughout the rest of 2013, the company got  
8 about trying to implement and strengthen its  
9 SOMS process, fair?  
10 MS. VANNI: Object to the  
11 colloquy. Object to form.  
12 THE WITNESS: We continued with  
13 our planned improvements.  
14 BY MR. BUCHANAN:  
15 Q. Okay. And you also discussed  
16 with defense counsel on direct examination the  
17 quota process.  
18 Do you recall that?  
19 A. I do.  
20 Q. The inner relation with the DEA  
21 going back and forth from time to time, and you  
22 said that was an important part of your  
23 responsibilities?  
24 A. Yes, it is -- was.

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1 MR. BUCHANAN: Could I have 1068,  
2 please. I need a copy for the witness.  
3 Could you take it down until I have  
4 copies for the witness, please.  
5 Counsel.  
6 (Document marked for  
7 identification as Par-Norton Deposition  
8 Exhibit No. 36.)  
9 BY MR. BUCHANAN:  
10 Q. We're marking this, ma'am, as  
11 Exhibit 39 (sic) to your deposition.  
12 A. Okay.  
13 Q. It's an e-mail from -- e-mail  
14 exchange between you and a few other folks at  
15 Qualitest, Sanjay Patel, yourself as the latest  
16 in time e-mail at the top, but there's an  
17 exchange going on regarding a quota request.  
18 You can go bottom up, but I suggest you can  
19 probably get all the information you need on the  
20 first page if you start at the bottom of the  
21 first. We're at 1068.1, and you received an  
22 e-mail from Fang Zhou?  
23 A. Fang Zhou.  
24 Q. Zhou. "Hi, Tracey. Please find

<p style="text-align: right;">Page 669</p> <p>1 the information below to apply the quote of  2 oxycodone hydrochloride for 2013. Would you  3 apply quota for 115 kg oxycodone hydrocodone  4 ASAP?"</p> <p>5 Did I read that correctly?</p> <p>6 A. Yes, you did.</p> <p>7 Q. And then it's got a list of the  8 various units and strengths.</p> <p>9 Do you see that?</p> <p>10 A. Yes.</p> <p>11 Q. Okay. And is this generally the  12 process, people throughout the organization with  13 various needs, whether it was research, whether  14 it was testing, whether it was sales for  15 production, would come to you and give you  16 numbers to apply to quota or to seek quota from  17 DEA if you needed more?</p> <p>18 MS. VANNI: Objection to form.</p> <p>19 THE WITNESS: For sales that was  20 not the process. We would look at our  21 sales using IMS data, and we would -- we  22 would submit quota using that  23 information. This is for research, and  24 in the research case, they will tell us</p>	<p style="text-align: right;">Page 671</p> <p>1 not sure asking for this in our current SOMS  2 environment, and your current SOMS environment  3 in early 2013, two months after you met with the  4 DEA, was a SOMS environment that you  5 characterized as weak and inadequate, right?</p> <p>6 MS. VANNI: Object to form.</p> <p>7 THE WITNESS: In that prior  8 document, that's how it was  9 characterized.</p> <p>10 BY MR. BUCHANAN:</p> <p>11 Q. That's right.</p> <p>12 And what you noted here is you  13 were, I guess, seeking input from your  14 colleague, Mr. Patel, was not sure asking for  15 this, and "this" would be a quota increase,  16 right?</p> <p>17 A. Yes.</p> <p>18 Q. "Not sure asking for this in the  19 company's current SOMS environment is the best  20 idea."</p> <p>21 Did I read that correctly?</p> <p>22 A. Yes, you did.</p> <p>23 Q. Thank you. You can set that  24 aside.</p>
<p style="text-align: right;">Page 670</p> <p>1 how much we need -- how much they need,  2 and it's our job to push back on that  3 quantity and to determine if that  4 actually is definitively needed.</p> <p>5 BY MR. BUCHANAN:</p> <p>6 Q. Okay. And so this is all  7 happening in mid-2013 a few months after your --  8 May 2013, a few months after your meeting with  9 DEA, correct?</p> <p>10 A. Yes.</p> <p>11 Q. Two months exactly.</p> <p>12 And your response is you forward  13 this to Mr. Patel is FYI, I guess you are  14 forwarding the thread to him for consideration?</p> <p>15 A. Yes.</p> <p>16 Q. FYI, for your information, is  17 that what that means?</p> <p>18 A. Yes, uh-huh.</p> <p>19 Q. "Not sure asking for this in" --  20 what did you write?</p> <p>21 A. "Not sure asking for this in our  22 current SOMS environment is the best idea.  23 Thoughts?"</p> <p>24 Q. Okay. Let's pause on that. So</p>	<p style="text-align: right;">Page 672</p> <p>1 You talked about some of the SOMS  2 processes the company engaged in in this 2013  3 and later period, consideration of information  4 and how that worked.</p> <p>5 You also formed a SOMS advisory  6 board, right?</p> <p>7 A. Yes, we did.</p> <p>8 Q. Okay.</p> <p>9 MR. BUCHANAN: Could I have 1148.  10 This will be Exhibit 43. Can we go off  11 the record.</p> <p>12 THE VIDEOGRAPHER: The time is  13 10:48. Off the record.</p> <p>14 (Document marked for  15 identification as Par-Norton Deposition  16 Exhibit No. 37.)</p> <p>17 THE VIDEOGRAPHER: The time is  18 10:50 a.m. We are back on the record.</p> <p>19 BY MR. BUCHANAN:</p> <p>20 Q. Passing you, ma'am, what we just  21 marked as Exhibit 37 to your record. Our  22 internal number is E1148. It's an exchange  23 between you and Mr. Brantley in 2014, early  24 2014.</p>

<p style="text-align: right;">Page 673</p> <p>1 Do you see that?</p> <p>2 A. Yes.</p> <p>3 Q. Okay. And he's passing on the</p> <p>4 charter for the advisory board of Qualitest</p> <p>5 Pharmaceuticals suspicious order monitoring</p> <p>6 program.</p> <p>7 Do you see that?</p> <p>8 A. Yes.</p> <p>9 Q. And you told us about some of</p> <p>10 these DEA interactions, where the DEA didn't</p> <p>11 want the sales team making calls on whether</p> <p>12 orders were suspicious and customers were</p> <p>13 suspicious, right?</p> <p>14 A. Correct.</p> <p>15 Q. Okay. You implemented this</p> <p>16 particular protocol in early 2014?</p> <p>17 A. This charter, yes, when it was</p> <p>18 finalized.</p> <p>19 Q. And so what we see here is</p> <p>20 there's the SOM team, which Mr. Brantley was a</p> <p>21 part of, correct?</p> <p>22 A. Yes.</p> <p>23 Q. There was an advisory board,</p> <p>24 correct?</p>	<p style="text-align: right;">Page 675</p> <p>1 various things or recommendations?</p> <p>2 A. Yes, that's correct.</p> <p>3 Q. Okay. And am I correct, though,</p> <p>4 that with regard to certain customers, customers</p> <p>5 that bought a lot of your product, that was not</p> <p>6 a decision made by the advisory board, right?</p> <p>7 MS. VANNI: Object to form.</p> <p>8 THE WITNESS: No, that's not</p> <p>9 correct.</p> <p>10 BY MR. BUCHANAN:</p> <p>11 Q. For tier 1 customers, ma'am, tier</p> <p>12 1 customers, decisions as to whether stop</p> <p>13 selling to them or reducing quota, those went to</p> <p>14 your chief operating officer, right?</p> <p>15 A. Where are you seeing this? Oh, I</p> <p>16 see, okay, yes.</p> <p>17 Q. I'm looking -- general advisory</p> <p>18 board responsibilities.</p> <p>19 Do you see that?</p> <p>20 A. I do.</p> <p>21 Q. Towards the bottom, "The general</p> <p>22 responsibilities and duties of the Advisory</p> <p>23 Board include: Review recommendations from the</p> <p>24 SOM team regarding corrective actions concerning</p>
<p style="text-align: right;">Page 674</p> <p>1 A. Yes.</p> <p>2 Q. And you were a component of the</p> <p>3 advisory board?</p> <p>4 A. I believe so. I don't know where</p> <p>5 the numbers are listed, but I believe yes.</p> <p>6 Q. It's on 1148.2, "Membership."</p> <p>7 A. Yes.</p> <p>8 Q. Okay. "The advisory board shall</p> <p>9 consist of the Director of DEA compliance."</p> <p>10 That was you, right?</p> <p>11 A. Yes.</p> <p>12 Q. "Vice President Legal," who was</p> <p>13 that?</p> <p>14 A. Margaret Richardson.</p> <p>15 Q. Okay. And the Deputy Compliance</p> <p>16 Officer for generics, right?</p> <p>17 A. Yes.</p> <p>18 Q. And who was that?</p> <p>19 A. Sandra Parker.</p> <p>20 Q. Okay. And so the advisory board</p> <p>21 would consider information given to it by the</p> <p>22 SOM team, correct?</p> <p>23 A. Correct.</p> <p>24 Q. And you guys would make calls on</p>	<p style="text-align: right;">Page 676</p> <p>1 tier 1 customers who are not in compliance with</p> <p>2 Qualitest SOM policies."</p> <p>3 Did I read that correctly?</p> <p>4 A. You did.</p> <p>5 Q. "A tier 1 customer is a customer</p> <p>6 with a minimum of ten million dollars in overall</p> <p>7 sales and/or 750,000 dosage units of Controlled</p> <p>8 Substance or List 1 chemical purchases</p> <p>9 annually."</p> <p>10 Did I read that correctly?</p> <p>11 A. You did.</p> <p>12 Q. And it says in the next sentence</p> <p>13 who would be responsible with regard to "final</p> <p>14 authority in determining Controlled Substance</p> <p>15 discontinuance to a tier 1 customer," correct?</p> <p>16 A. Yes.</p> <p>17 Q. And the person who had that</p> <p>18 responsibility was not the DEA compliance</p> <p>19 officer, correct?</p> <p>20 A. No.</p> <p>21 MS. VANNI: Object to form.</p> <p>22 THE WITNESS: The DEA compliance</p> <p>23 officer reviewed with the rest of the</p> <p>24 team members the advisory board and then</p>



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1 the recommendation would be sent to the  
2 quality chief operating officer.  
3 BY MR. BUCHANAN:  
4 Q. Right. The chief operating  
5 officer, correct?  
6 A. Yes.  
7 Q. And who was that at this point in  
8 time?  
9 A. I think it was Don Degoyla at  
10 that time.  
11 Q. Chief operating officer is a  
12 business guy, right?  
13 MS. VANNI: Object to form.  
14 THE WITNESS: Yes.  
15 BY MR. BUCHANAN:  
16 Q. Okay. And so the business guy  
17 who was above you in the org chart had the final  
18 authority for determining whether or not you  
19 were going to discontinue sales to your really  
20 big customers, right?  
21 MS. VANNI: Object to form.  
22 THE WITNESS: He had the final  
23 say once all information was provided to  
24 him, and, obviously, he would want to

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1 comply with the DEA regulation as the  
2 chief operating officer.  
3 BY MR. BUCHANAN:  
4 Q. Oh, you certainly go beyond my  
5 question.  
6 My question to you was who had  
7 the final authority in terms of discontinuing  
8 controlled substance sales to your big  
9 customers?  
10 MS. VANNI: Object to colloquy.  
11 THE WITNESS: He did.  
12 BY MR. BUCHANAN:  
13 Q. He did, the chief operating  
14 officer, the business guy?  
15 MS. VANNI: Objection.  
16 THE WITNESS: Because there  
17 was -- would be a business --  
18 BY MR. BUCHANAN:  
19 Q. Is that a yes answer, ma'am? I  
20 need a yes answer.  
21 A. Yes, it is, yes.  
22 Q. Thank you.  
23 You spent some time with defense  
24 counsel on Exhibit 5, our internal number is 594

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1 on this one.  
2 Do you have Exhibit 5 before you?  
3 We can work with the screen.  
4 Here you go.  
5 Exhibit 5 is that letter that you  
6 sent out to your customers in 2013.  
7 Do you recall that?  
8 A. I do.  
9 Q. And I think you called out the  
10 questionnaire in the back and a portion of the  
11 description of some of the changes you were  
12 making.  
13 Do you recall that?  
14 A. I do.  
15 Q. Okay. But what you noted in the  
16 paragraph before that, this is 594.3, it's  
17 beginning "when our products."  
18 "When our products leave the  
19 legitimate channels they have been manufactured  
20 to support, heart-wrenching consequences often  
21 occur."  
22 Do you see that?  
23 A. Yes, we've read it several times.  
24 Q. "As responsible corporate

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1 citizens -- individuals, parents, friends,  
2 caregivers, relatives and acquaintances -- we  
3 need to do as much as we can to prevent drug  
4 abuse and diversion in our communities."  
5 Did I read that correctly?  
6 A. Yes.  
7 Q. "Each company and individual in  
8 the supply chain has that responsibility."  
9 Did I read that correctly?  
10 A. Yes.  
11 Q. "To put adequate controls in  
12 place to discourage and prevent the diversion of  
13 prescription products for uses other than those  
14 for which they were originally intended."  
15 Did I read that correctly?  
16 A. Yes, you did.  
17 MS. VANNI: Just note my  
18 objection, just beyond the scope. I  
19 know I used this document on direct, but  
20 I didn't refer her to that paragraph or  
21 ask her any questions about that part --  
22 MR. BUCHANAN: I understand your  
23 objection. I don't know how video will  
24 get cut at some point in time.

<p style="text-align: right;">Page 681</p> <p>1 MS. VANNI: Just preserving my  2 objection.  3 MR. BUCHANAN: Fair enough.  4 BY MR. BUCHANAN:  5 Q. Let's look at -- well, withdrawn.  6 In examination I think both with  7 Endo counsel and Anda counsel, you were asked  8 about compliance with the reg, whether acts were  9 in compliance or not with the reg regarding  10 suspicious orders, and I think you were even  11 shown the statute.  12 Do you recall that?  13 A. Yes.  14 Q. Okay. We looked yesterday, just  15 in passing, at a letter that you received from  16 DEA in 2007, you, obviously at a former company  17 at that point in time, from Mr. Rannazzisi.  18 Do you recall that?  19 A. I do.  20 Q. And you remember receiving that  21 letter?  22 A. I remember seeing the letter,  23 yes.  24 Q. Okay.</p>	<p style="text-align: right;">Page 683</p> <p>1 Q. Is this the same letter ma'am  2 that we saw in the PowerPoint yesterday that you  3 had referenced from your time at the company?  4 A. I believe it's the same letter.  5 Q. And so this is December 27, 2007,  6 several years before you joined the company,  7 correct?  8 A. Yes.  9 Q. And you acknowledge being aware  10 or at least having received it during your time  11 at a prior employer, correct?  12 A. I had seen it, yes.  13 Q. Okay. And this went to  14 manufacturers and distributors, right?  15 A. Yes.  16 Q. "The purpose of this letter is to  17 reiterate the responsibilities of controlled  18 substance manufacturers and distributors to  19 inform DEA of suspicious orders in accordance  20 with 21 CFR 1301.74(b)."  21 Do you see that?  22 A. Yes I do.  23 Q. I'd like to focus on the next  24 paragraph. It says, "In addition to, and not in</p>
<p style="text-align: right;">Page 682</p> <p>1 MR. BUCHANAN: Let's look at  2 Exhibit -- internal Exhibit Number 640.  3 (Document marked for  4 identification as Par-Norton Deposition  5 Exhibit No. 38.)  6 BY MR. BUCHANAN:  7 Q. Passing you what we're marking as  8 Exhibit 38.  9 MR. BUCHANAN: Copy for defense  10 counsel, please.  11 BY MR. BUCHANAN:  12 Q. And this is some internal  13 correspondence with Endo from before your time  14 there, attaching a letter that had been received  15 from a Mr. Rannazzisi, "Dear Registrant."  16 Do you see that?  17 A. Yes.  18 MS. VANNI: I just want to note  19 my objection to use of this document as  20 it predates her employment with the  21 company, and it's an Endo document, so  22 it doesn't even apply to her employment  23 since she wasn't an Endo employee.  24 BY MR. BUCHANAN:</p>	<p style="text-align: right;">Page 684</p> <p>1 lieu of, the general requirement under 21 USC  2 823, that manufacturers and distributors  3 maintain effective controls against diversion,"  4 and then the sentence continues.  5 This letter is telling  6 registrants that in addition to obligation, the  7 statutory obligation to maintain effective  8 controls against diversion, there are some other  9 things we want to highlight to you about  10 suspicious order monitoring practices, fair?  11 MS. VANNI: Object to form.  12 THE WITNESS: It refers back to  13 the regulation, the CFR, yes.  14 BY MR. BUCHANAN:  15 Q. Is that a yes to my question?  16 MS. VANNI: Object to form.  17 THE WITNESS: No, I'm not sure.  18 BY MR. BUCHANAN:  19 Q. Okay. Well, you said, I think,  20 in the examination with defense counsel that you  21 took your communications from DEA as guidance,  22 correct?  23 A. I did.  24 Q. Oral communications as guidance,</p>

<p style="text-align: right;">Page 685</p> <p>1 correct?</p> <p>2 A. Yes.</p> <p>3 Q. I think you were even told that</p> <p>4 DEA presentations were guidance as to</p> <p>5 compliance, correct?</p> <p>6 MS. VANNI: Object to form.</p> <p>7 THE WITNESS: All instructions</p> <p>8 from DEA are -- have meaning to me, and</p> <p>9 I take them seriously, yes.</p> <p>10 BY MR. BUCHANAN:</p> <p>11 Q. Well, in fact, they told you when</p> <p>12 you sat down with them and we looked at it</p> <p>13 yesterday in the minutes of the meeting with the</p> <p>14 DEA in 2013 that all that information I just</p> <p>15 discussed, presentations, letters, statements</p> <p>16 and communications with the DEA, that was all</p> <p>17 guidance for you to incorporate as part of your</p> <p>18 compliance program, correct?</p> <p>19 MS. VANNI: Object to form.</p> <p>20 THE WITNESS: They were</p> <p>21 suggestions for things that industry</p> <p>22 could use, yes.</p> <p>23 BY MR. BUCHANAN:</p> <p>24 Q. We're circle back on the minutes</p>	<p style="text-align: right;">Page 687</p> <p>1 MS. VANNI: Object to form.</p> <p>2 MR. BUCHANAN: Ma'am, move to</p> <p>3 strike the nonresponsive portion. I'm</p> <p>4 not asking whether and you were. You</p> <p>5 keep inserting that at the end. I'm</p> <p>6 supposing that maybe that's guidance.</p> <p>7 Let's stay with my questions, okay.</p> <p>8 MS. VANNI: Object to the</p> <p>9 colloquy, and I just want to note that</p> <p>10 you are at 35 minutes for Endo.</p> <p>11 MR. BUCHANAN: I'm at 35 minutes</p> <p>12 of an hour and 20 minutes.</p> <p>13 BY MR. BUCHANAN:</p> <p>14 Q. In addition to, you understand to</p> <p>15 mean in addition to the statutory requirements,</p> <p>16 correct?</p> <p>17 MS. VANNI: Counsel, I'm sorry.</p> <p>18 Just for -- I'm sorry. I didn't mean to</p> <p>19 interrupt you. Just for clarification,</p> <p>20 is it your position that you're entitled</p> <p>21 to use the full direct, not minute for</p> <p>22 minute as used by the defendants on</p> <p>23 direct?</p> <p>24 MR. BUCHANAN: I am entitled to</p>
<p style="text-align: right;">Page 686</p> <p>1 in a moment.</p> <p>2 What this letter is -- and so</p> <p>3 this would be guidance to you, this letter,</p> <p>4 correct?</p> <p>5 A. Yes.</p> <p>6 Q. As to what the DEA was expecting</p> <p>7 of you as a registrant, correct?</p> <p>8 A. Yes.</p> <p>9 Q. Okay. And so it says "In</p> <p>10 addition to, and not in lieu of."</p> <p>11 Do you have an understanding what</p> <p>12 that means?</p> <p>13 A. I do.</p> <p>14 Q. And what does it mean?</p> <p>15 A. It means instead of versus, yeah,</p> <p>16 this end instead -- you can't substitute one for</p> <p>17 the other.</p> <p>18 Q. That's right. I mean, you have</p> <p>19 an obligation, obviously, to do suspicious order</p> <p>20 monitoring, and you have an obligation to</p> <p>21 maintain effective controls against diversion,</p> <p>22 correct?</p> <p>23 A. Absolutely and we were.</p> <p>24 MS. KOSKI: Object.</p>	<p style="text-align: right;">Page 688</p> <p>1 use minute for minute of the redirect</p> <p>2 examination conducted by you or your</p> <p>3 direct examination used by you.</p> <p>4 MS. VANNI: That would be 35</p> <p>5 minutes for Endo.</p> <p>6 MR. BUCHANAN: No, I mean "you"</p> <p>7 as defendants.</p> <p>8 MS. VANNI: Okay. We object to</p> <p>9 that position, but -- so just note our</p> <p>10 objection.</p> <p>11 MR. BUCHANAN: That hasn't been</p> <p>12 my understanding, but I've been doing</p> <p>13 issues that concern Anda as part of</p> <p>14 this. I'm not sequencing specifically</p> <p>15 between Anda and Endo.</p> <p>16 BY MR. BUCHANAN:</p> <p>17 Q. This Rannazzisi letter that was</p> <p>18 received in 2007 by registrants, and we saw it</p> <p>19 copied in your PowerPoint, reflects that the</p> <p>20 requirements under the CFR are in addition to</p> <p>21 and not in lieu of those in the statute,</p> <p>22 correct?</p> <p>23 A. That's what it says.</p> <p>24 Q. Thank you.</p>

<p style="text-align: right;">Page 689</p> <p>1 And let's look at that with                  2 regard to -- so a manufacturer or a distributor                  3 has an obligation to maintain effective controls                  4 against diversion, right?                  5 A. Yes, as identified in the                  6 regulation.                  7 Q. Statutory -- I'm sorry. As                  8 identified in the statute?                  9 A. Yes.                  10 Q. Okay. Has an obligation to                  11 maintain effective controls against diversion,                  12 that's the statutory obligation, correct?                  13 A. Yes.                  14 Q. And Mr. Rannazzisi is saying you                  15 have a separate obligation with regard to the                  16 CFR, the regulation, with regard to suspicious                  17 order monitoring and reporting, correct?                  18 MS. KOSKI: Object to form.                  19 MS. VANNI: Object to form.                  20 THE WITNESS: Yes.                  21 BY MR. BUCHANAN:                  22 Q. Okay. And so in this letter -- I                  23 mean, you'd agree this is important guidance                  24 from DEA, correct?</p>	<p style="text-align: right;">Page 691</p> <p>1 A. Yes.                  2 Q. Okay. "The determination of                  3 whether an order is suspicious depends not only                  4 on the ordering patterns of the particular                  5 customer, but also on the patterns of the                  6 registrant's customer base and the patterns                  7 throughout the relevant segment of the regulated                  8 industry."                  9 Did I read that correctly?                  10 A. Yes.                  11 Q. Okay. So what this is saying is,                  12 one, your system has got to look at patterns,                  13 right?                  14 MS. VANNI: Object to form.                  15 BY MR. BUCHANAN:                  16 Q. Isn't that what he wrote?                  17 A. It says if you're looking at                  18 patterns, the size of the order alone is                  19 different than -- basically that they're not --                  20 you can't base a decision on one versus the                  21 other.                  22 Q. Let's look at what's written by                  23 the DEA to registrants.                  24 "The determination of whether an</p>
<p style="text-align: right;">Page 690</p> <p>1 MS. VANNI: Object to form.                  2 THE WITNESS: It's guidance.                  3 It's not anything that wasn't well known                  4 at the time.                  5 BY MR. BUCHANAN:                  6 Q. Okay. Well, let's see what was,                  7 again, then well known at the time before you                  8 got this letter.                  9 "The regulation specifically                  10 states that suspicious orders include orders of                  11 unusual size, orders deviating from a normal                  12 pattern and orders of an unusual frequency."                  13 Would you agree that's what he                  14 wrote?                  15 A. That's what it says, yes.                  16 Q. Can you go to third paragraph,                  17 please. It continue, "The size of order alone,                  18 whether or not it deviates from a normal                  19 pattern, is enough to trigger the registrant's                  20 responsibility to report the order as                  21 suspicious."                  22 Do you see that? It's the --                  23 sorry, fourth paragraph.                  24 Do you see that, ma'am?</p>	<p style="text-align: right;">Page 692</p> <p>1 order is suspicious depends not only on the                  2 ordering patterns of the particular customer,                  3 but also on the patterns of the registrant's                  4 customer base and the patterns throughout the                  5 relevant segment of the regulated industry."                  6 Did I read that correctly?                  7 A. You read it correctly.                  8 Q. Okay. And as of the time you got                  9 to Qualitest, was the Qualitest suspicious order                  10 monitoring system looking at class of trade as                  11 separate thresholds?                  12 A. Again, I can't comment on what                  13 the system was --                  14 MS. VANNI: Objection.                  15 THE WITNESS: -- before I got                  16 there.                  17 MS. VANNI: Beyond the scope.                  18 BY MR. BUCHANAN:                  19 Q. At the time you got there. At                  20 the time you got there, ma'am, was it looking at                  21 relevant classes of trade?                  22 MS. VANNI: Objection, asked and                  23 answered.                  24 THE WITNESS: I don't know what</p>

<p style="text-align: right;">Page 693</p> <p>1 OMS was doing.  2 BY MR. BUCHANAN:  3 Q. Okay. The next page it says,  4 "Registrants that rely on rigid formulas to  5 define whether an order is suspicious may be  6 failing to detect suspicious orders."  7 Did I read that correctly?  8 A. You did.  9 Q. "For example, a system that  10 identifies orders as suspicious only if the  11 total amount of a controlled substance order  12 during one month exceeds the amount ordered the  13 previous month by a certain percentage or more  14 is" -- what did Mr. Rannazzisi say?  15 A. "Is insufficient."  16 Q. "Is insufficient." So you had  17 that knowledge as of 2007, right?  18 MS. VANNI: Object to form.  19 THE WITNESS: In other words,  20 don't rely on pattern.  21 BY MR. BUCHANAN:  22 Q. It says something that is looking  23 at whether or not it just exceeds a  24 predetermined percentage from a prior month is</p>	<p style="text-align: right;">Page 695</p> <p>1 Q. Nonetheless, you had this  2 guidance from the DEA as of the end of 2007, and  3 I think you even said this was known before,  4 right?  5 MS. KOSKI: Object to form.  6 MS. VANNI: Object to form.  7 THE WITNESS: The letter was out  8 there.  9 BY MR. BUCHANAN:  10 Q. And, "Also, this system would not  11 identify orders as suspicious if the order were  12 solely for one highly abused controlled  13 substance if the orders never grew  14 substantially."  15 Did I read that correctly?  16 A. You did.  17 Q. "Nevertheless, ordering one  18 highly abused controlled substance and little or  19 nothing else deviates from the normal pattern of  20 what pharmacies generally order."  21 Did I read that correctly?  22 A. You did.  23 Q. This is that product mix issue  24 that the DEA discussed with you later in time,</p>
<p style="text-align: right;">Page 694</p> <p>1 insufficient, correct?  2 A. Which is the frequency of the  3 order. That's what it says, yes.  4 Q. "A system that identifies orders  5 as suspicious only if the total amount of a  6 controlled substance ordered during one month  7 exceeds the amount ordered the previous month by  8 a certain percentage or more is insufficient."  9 Those are the words, right?  10 MS. VANNI: Object to form.  11 THE WITNESS: That's what it  12 says, yes.  13 BY MR. BUCHANAN:  14 Q. Okay. "This system fails to  15 identify orders placed by a pharmacy if the  16 pharmacy placed unusually large orders from the  17 beginning of its relationship with the  18 distributor."  19 Do you agree with that, ma'am?  20 A. That's what it says.  21 Q. Okay. And you agree?  22 MS. LEIBELL: Object to form.  23 THE WITNESS: No.  24 BY MR. BUCHANAN:</p>	<p style="text-align: right;">Page 696</p> <p>1 correct?  2 MS. KOSKI: Object to form.  3 MS. VANNI: Object to form.  4 THE WITNESS: I can't -- can't  5 connect the two.  6 BY MR. BUCHANAN:  7 Q. Okay. Well, let's talk about it.  8 "Ordering one highly abused controlled substance  9 and little or nothing else deviates from the  10 normal pattern of what pharmacies generally  11 order."  12 Did I read that correctly?  13 A. He's making a statement about  14 pharmacies. I mean, I think you're reading more  15 into what he's saying than is there but...  16 Q. You told us, ma'am, that these  17 are important guidances, and this is what you  18 governed your actions by, right?  19 MS. KOSKI: Object to form.  20 MS. VANNI: Object to form.  21 THE WITNESS: They are things  22 that I take into consideration, yes.  23 BY MR. BUCHANAN:  24 Q. Well, if the DEA is telling you</p>



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1 this is what you need to do to comply, then this  
2 is what you need to do to comply, right?  
3 MS. KOSKI: Object to form.  
4 THE WITNESS: And we did.  
5 BY MR. BUCHANAN:  
6 Q. Okay. And so Qualitest was  
7 considering the relative percentages of  
8 controlled substances versus noncontrolled  
9 substances of its customers prior to 2013,  
10 ma'am?  
11 A. I don't know, again, what OMS was  
12 doing.  
13 Q. Okay. You're not aware that  
14 Qualitest was doing that, correct?  
15 MS. VANNI: Object to form.  
16 THE WITNESS: I don't know. I  
17 can't comment.  
18 BY MR. BUCHANAN:  
19 Q. Okay. You have no information to  
20 share with us as to whether Qualitest was doing  
21 that, correct?  
22 MS. VANNI: Object to form.  
23 THE WITNESS: Do not, no.  
24 BY MR. BUCHANAN:

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1 Q. Okay. Paragraph beginning  
2 "lastly."  
3 Lastly, registrants that  
4 routinely report suspicious orders, yet fill  
5 these orders without first determining that the  
6 order is not being diverted into other than  
7 legitimate medical scientific and industrial  
8 channels may be failing to maintain effective  
9 controls against diversion.  
10 Did I read that correctly?  
11 A. Yes, you did.  
12 Q. And you have that knowledge and  
13 understanding as of 2007 at the latest, ma'am?  
14 MS. VANNI: Object to form.  
15 THE WITNESS: That's what he's  
16 saying in 2007, yes.  
17 BY MR. BUCHANAN:  
18 Q. And he is the DEA at this point?  
19 A. Yes.  
20 Q. Okay. And this is a DEA  
21 communication to all registrants, correct?  
22 MS. KOSKI: Object to form.  
23 THE WITNESS: It is a  
24 communication to some registrants, yes.

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1 MR. BUCHANAN: Okay.  
2 THE WITNESS: Manufacturers and  
3 distributors.  
4 BY MR. BUCHANAN:  
5 Q. Fair enough, to manufacturers and  
6 distributors. Okay.  
7 All right. So every year that  
8 Qualitest or any of the entities you were with  
9 filed a application with the DEA to get  
10 permission to manufacture, to distribute, to  
11 sell controlled substances, you were agreeing to  
12 play within that framework, right?  
13 MS. KOSKI: Object to form.  
14 MS. VANNI: Objection.  
15 THE WITNESS: We were agreeing to  
16 abide by the DEA regulations.  
17 BY MR. BUCHANAN:  
18 Q. You were agreeing to maintain  
19 effective controls against diversion, one,  
20 correct?  
21 MS. VANNI: Objection.  
22 THE WITNESS: Which we did, yes.  
23 All of the recordkeeping and  
24 accountability and storage requirements

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1 were met.  
2 MR. BUCHANAN: Move to strike.  
3 You did it again. Let's stay with my  
4 question.  
5 MS. KOSKI: Objection.  
6 BY MR. BUCHANAN:  
7 Q. When you apply for a  
8 registration, you are agreeing to maintain  
9 effective controls against diversion, correct?  
10 A. Yes, and we did.  
11 MR. BUCHANAN: Move to strike.  
12 BY MR. BUCHANAN:  
13 Q. Are you having a hard time just  
14 staying with my focus?  
15 MS. VANNI: Object to colloquy.  
16 BY MR. BUCHANAN:  
17 Q. Are you having a hard time with  
18 that?  
19 A. No.  
20 Q. Okay. When you file an  
21 application with the DEA to be a registrant as  
22 either a manufacturer or a distributor, you are  
23 agreeing that you will maintain effective  
24 controls to prevent diversion, yes or no?

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<p>1 A. Yes.</p> <p>2 MS. VANNI: Objection, asked and</p> <p>3 answered.</p> <p>4 BY MR. BUCHANAN:</p> <p>5 Q. When you make an application to</p> <p>6 be a registrant, you are agreeing that you will</p> <p>7 comply with the regulations concerning</p> <p>8 suspicious order monitoring, yes or no?</p> <p>9 MS. KOSKI: Objection to form.</p> <p>10 MS. VANNI: Objection, asked and</p> <p>11 answered.</p> <p>12 THE WITNESS: Yes.</p> <p>13 BY MR. BUCHANAN:</p> <p>14 Q. You agree not just the first</p> <p>15 time, you agree every time you do that; yes or</p> <p>16 no?</p> <p>17 MS. VANNI: Objection.</p> <p>18 THE WITNESS: Yes.</p> <p>19 BY MR. BUCHANAN:</p> <p>20 Q. And so if you're agreeing to do</p> <p>21 that, it's not unreasonable for the DEA to</p> <p>22 believe that you're doing that, correct?</p> <p>23 MS. VANNI: Objection.</p> <p>24 THE WITNESS: Yes, and to</p>	<p>1 order monitoring program to detect suspicious</p> <p>2 orders, correct?</p> <p>3 MS. KOSKI: Objection.</p> <p>4 MS. VANNI: Objection, asked and</p> <p>5 answered.</p> <p>6 THE WITNESS: As done, yes.</p> <p>7 MR. BUCHANAN: Move to strike.</p> <p>8 BY MR. BUCHANAN:</p> <p>9 Q. And you also had the obligation,</p> <p>10 and you agreed every time you renewed, that you</p> <p>11 were maintaining a suspicious order monitoring</p> <p>12 program compliant with the DEA guidance,</p> <p>13 correct?</p> <p>14 MS. KOSKI: Object to form.</p> <p>15 MS. VANNI: Objection.</p> <p>16 THE WITNESS: Yes.</p> <p>17 BY MR. BUCHANAN:</p> <p>18 Q. And if you weren't doing so, and</p> <p>19 if you weren't doing so, that would be a very</p> <p>20 serious breach of not only the promise you made</p> <p>21 as part of your registration but also the public</p> <p>22 trust, yes or no?</p> <p>23 MS. KOSKI: Objection.</p> <p>24 MS. VANNI: Objection.</p>
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<p>1 inspect, to confirm.</p> <p>2 BY MR. BUCHANAN:</p> <p>3 Q. You saw the interaction with the</p> <p>4 DEA yesterday, where you were told that you had</p> <p>5 the public trust in your hands.</p> <p>6 Do you recall hearing that from</p> <p>7 the DEA in 2013?</p> <p>8 A. Yes.</p> <p>9 MS. VANNI: Objection.</p> <p>10 BY MR. BUCHANAN:</p> <p>11 Q. You had that understanding as a</p> <p>12 DEA compliance officer, correct?</p> <p>13 A. Yes.</p> <p>14 Q. That not just -- the obligation</p> <p>15 wasn't just to make the pills and put them out</p> <p>16 there, but to maintain effective controls</p> <p>17 against diversion when you were doing that.</p> <p>18 You understood that, correct?</p> <p>19 MS. VANNI: Object to form.</p> <p>20 THE WITNESS: Yes.</p> <p>21 BY MR. BUCHANAN:</p> <p>22 Q. And to maintain appropriate --</p> <p>23 withdrawn.</p> <p>24 And to maintain a suspicious</p>	<p>1 THE WITNESS: That would be not</p> <p>2 complying with the regulation.</p> <p>3 BY MR. BUCHANAN:</p> <p>4 Q. And a breach of the public trust;</p> <p>5 do you agree with that?</p> <p>6 MS. VANNI: Objection.</p> <p>7 THE WITNESS: It's not up to me</p> <p>8 to define what's a breach of the public</p> <p>9 trust.</p> <p>10 BY MR. BUCHANAN:</p> <p>11 Q. You understand that you can't</p> <p>12 do -- you being Qualitest, a manufacturer and</p> <p>13 distributor of controlled substances during the</p> <p>14 time you were there or with any of the</p> <p>15 manufacturers and distributors that you worked</p> <p>16 with, you can't do what you do without the</p> <p>17 permission slip that's obtained following the</p> <p>18 promise you make to do those things, right?</p> <p>19 MS. VANNI: Object to form.</p> <p>20 THE WITNESS: Following the grant</p> <p>21 of the license by DEA.</p> <p>22 BY MR. BUCHANAN:</p> <p>23 Q. And the promise that the</p> <p>24 registrant will maintain effective controls</p>

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1 against diversion and a suspicious order  
2 monitoring program to detect suspicious orders;  
3 you would agree, correct?  
4 MS. VANNI: Object to form.  
5 THE WITNESS: We have to comply  
6 with the regulations.  
7 MS. VANNI: My real time is down.  
8 Could we go off the record.  
9 THE VIDEOGRAPHER: The time is  
10 now 11:15 a.m. We are off the record.  
11 (Pause.)  
12 THE VIDEOGRAPHER: The time is  
13 11:18. We are back on the record.  
14 BY MR. BUCHANAN:  
15 Q. Ma'am, you have 640.1 before you.  
16 Let me just see the exhibit number, though.  
17 Internal Number 640.1, 38 for the deposition.  
18 MR. BUCHANAN: Could we pull up  
19 that one.  
20 MS. VANNI: Could I have a copy?  
21 MR. BUCHANAN: You have it. It's  
22 already been marked.  
23 BY MR. BUCHANAN:  
24 Q. So on Exhibit 38 on the first

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1 page, ma'am, I understand you were not at  
2 Qualitest at this point in time.  
3 Did you have familiarity with the  
4 HDMA?  
5 A. Not at this time, no.  
6 Q. When did you get involved with  
7 HDMA?  
8 A. When I worked for HD Smith.  
9 Q. Okay. So at a late -- roughly  
10 ten years later, I guess?  
11 A. Yes.  
12 Q. Or eight years later, whatever it  
13 is.  
14 This e-mail notes that the HDMA,  
15 that's from Brian Munroe to a distribution list  
16 of people that probably included some and didn't  
17 include others from your time at Endo and  
18 Qualitest, he was the vice president of  
19 government affairs.  
20 Did you have any opportunity to  
21 deal with him during your time at Qualitest?  
22 A. I did.  
23 Q. Okay. I understood he had  
24 relations and interactions with HDMA on various

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1 issues?  
2 MS. VANNI: Object to form.  
3 THE WITNESS: I don't know.  
4 BY MR. BUCHANAN:  
5 Q. What he notes in this e-mail, can  
6 we have it on the screen here, "The HDMA is  
7 objecting to the attached DEA notice and is  
8 presenting to the Pain Care Forum tomorrow."  
9 Did I read that correctly?  
10 A. You did.  
11 Q. The attached notice is the notice  
12 we were looking at from Mr. Rannazzisi and the  
13 DEA in 2007, correct?  
14 A. Yes.  
15 Q. Okay. Did you know that that was  
16 one of the things HDMA was doing with regard to  
17 the guidances industry was receiving concerning  
18 suspicious order monitoring and anti-diversion  
19 efforts?  
20 A. No, I wasn't --  
21 MS. VANNI: Object to form.  
22 MR. LEEDER: Object to form.  
23 THE WITNESS: -- involved and  
24 didn't have knowledge of that.

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1 BY MR. BUCHANAN:  
2 Q. Did you know industry was  
3 objecting --  
4 A. No.  
5 MS. VANNI: Object to form.  
6 BY MR. BUCHANAN:  
7 Q. -- to the DEA's requirements?  
8 A. No, I did not.  
9 Q. Okay. "This is worth looking at  
10 as it represents the continuing 'creep' of the  
11 DEA into activities that contribute to the  
12 overall chilling effect of prescribing pain  
13 medications."  
14 Did I read that correctly?  
15 A. You did.  
16 Q. Okay. And were you involved at  
17 all with HDMA in trying to combat DEA  
18 regulations?  
19 A. No.  
20 MS. VANNI: Object to form.  
21 BY MR. BUCHANAN:  
22 Q. Okay. Or guidances?  
23 A. No.  
24 Q. Okay. Were you a part of Watson

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1 or Anda's efforts with the HDMA at this point in  
2 time?  
3 A. No.  
4 MS. KOSKI: Object to form.  
5 MS. LEIBELL: Object to form.  
6 BY MR. BUCHANAN:  
7 Q. Okay. Did you tell your peers at  
8 Watson or Anda at that point in time we've got  
9 to resist this obligation for our companies?  
10 A. No.  
11 MS. LEIBELL: Object to form.  
12 MS. KOSKI: Object to form.  
13 BY MR. BUCHANAN:  
14 Q. Did you know that others were  
15 doing that?  
16 A. I did not.  
17 Q. Okay. You talked about other  
18 industry organizations in your direct  
19 examination with Endo counsel. I think you  
20 mentioned the Anti-Diversion Industry Working  
21 Group, a red flags video.  
22 Do you recall that?  
23 A. I do.  
24 Q. Pass you what we're marking as

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1 Exhibit -- it's internal number 1080 for the  
2 deposition -- 39.  
3 (Document marked for  
4 identification as Par-Norton Deposition  
5 Exhibit No. 39.)  
6 BY MR. BUCHANAN:  
7 Q. Passing you Exhibit 39 to your  
8 deposition. There you go. This is a press  
9 release that issued around the time the red flag  
10 video was released; is that right?  
11 A. Yes.  
12 Q. And we looked at a document  
13 yesterday concerning the anti-diversion working  
14 group, where there was a reference to maybe we  
15 should do something like this.  
16 Do you recall that?  
17 A. I'm sorry?  
18 Q. I said we looked at a -- I think  
19 it was a meeting of -- your minutes having  
20 attended an anti-diversion working group meeting  
21 where, among other things, one thing that was  
22 discussed was the development of this video?  
23 A. Yes.  
24 Q. Okay. So that occurs and the

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1 video issues, right?  
2 A. Yes.  
3 Q. Were you a part of the review  
4 process for the red flag video, ma'am?  
5 A. I was.  
6 Q. I see Qualitest was also  
7 involved?  
8 A. Yes, when I worked for Qualitest.  
9 Q. Okay. And that was --  
10 A. That's me.  
11 Q. You're actually referenced on the  
12 press release announcing the red flag video?  
13 A. Yes.  
14 Q. And so you endorsed its content?  
15 MS. VANNI: Object to form.  
16 THE WITNESS: I did.  
17 BY MR. BUCHANAN:  
18 Q. You reviewed its contents?  
19 A. Yes.  
20 Q. Okay. And then you sent it  
21 around to others in the company as a -- to show  
22 them, frankly, what the anti-diversion working  
23 group had done?  
24 A. Yes.

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1 MR. BUCHANAN: Do we have a copy  
2 of the video I can give to counsel? I  
3 need a copy of the video, though, just  
4 for the record.  
5 (Thumb drive marked for  
6 identification as Par-Norton Deposition  
7 Exhibit No. 40.)  
8 MR. BUCHANAN: All right. I'm  
9 just marking as Exhibit 40 a thumb drive  
10 which has a copy of the video. I'd like  
11 you to watch with me now as we pull it  
12 up on the screen.  
13 Can you pull the red flag video  
14 up on the screen. Can you go to the  
15 start of it first, and let's just get it  
16 rolling for a moment. Can you  
17 transcribe what's played.  
18 (Video played as follows:  
19 "I'm Carmen Collazo, executive  
20 director for the examination" --  
21 MR. BUCHANAN: Let's pause. We  
22 don't have enough volume.  
23 THE VIDEOGRAPHER: The time is  
24 11:24. Off the record.

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1 (Brief recess.)  
2 THE VIDEOGRAPHER: The time is  
3 11:30. We are back on the record.  
4 BY MR. BUCHANAN:  
5 Q. Ma'am, you were telling us  
6 yesterday about your involvement with the  
7 anti-diversion working group. You also just  
8 discussed with us your involvement with the  
9 preparation of the red flag video both  
10 individually and on behalf of Qualitest.  
11 Do you recall that testimony?  
12 A. I do.  
13 Q. Okay. I'd like to just put it on  
14 the screen and just confirm that we're talking  
15 about the same thing, okay?  
16 A. Yes.  
17 MR. BUCHANAN: Can you queue it  
18 up please and pause for a second.  
19 BY MR. BUCHANAN:  
20 Q. This is NABP red flag video. You  
21 saw the title flash on the screen, ma'am?  
22 A. I did.  
23 Q. Okay. And you recognize this  
24 individual?

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1 A. Yes.  
2 Q. And who is he?  
3 A. Carmen Collazo, the head of the  
4 National Association of Boards of Pharmacy.  
5 Q. Could we go to -- we don't have  
6 the time to listen to all 12 minutes. We're  
7 going to hit a few places. But fair to say that  
8 what's happening here is the company is  
9 presenting -- I'm sorry -- the anti-diversion  
10 working group together with the ABMP is  
11 presenting situations and scenarios that may  
12 occur in pharmacies to sensitize pharmacists and  
13 pharmacies to maybe things they can do to help  
14 prevent diversion.  
15 A. Yes.  
16 Q. Would that be fair?  
17 MS. VANNI: Object to form.  
18 MR. BUCHANAN: Let's go to 2:21.  
19 Okay. That's actually helpful. That  
20 will refresh the witness' recollection  
21 more broadly.  
22 BY MR. BUCHANAN:  
23 Q. And one of the things the video  
24 did and we see it on the screen right now is

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1 show actually faces of individuals struggling  
2 with opioids, right?  
3 MS. BANNI: Object to form.  
4 THE WITNESS: Yes.  
5 BY MR. BUCHANAN:  
6 Q. One of the points being, these  
7 are everyday people who are addicted?  
8 A. That's the point --  
9 MS. BANNI: Object to form.  
10 THE WITNESS: -- yes.  
11 BY MR. BUCHANAN:  
12 Q. The point of showing faces of all  
13 ilks is to say this is a drug abuse issue that  
14 is different than drug abuse that people might  
15 ordinarily be thinking of, right?  
16 MS. KOSKI: Object to form.  
17 MS. BANNI: Object to form.  
18 THE WITNESS: I'm not sure, but  
19 it's meant to show that there are  
20 different types of people who face  
21 addiction.  
22 BY MR. BUCHANAN:  
23 Q. And the jury will have the full  
24 video to review and see what was trying to be

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1 conveyed --  
2 A. Yes.  
3 Q. -- by the anti-diversion working  
4 group, together in collaboration with the ABMP,  
5 but I would like to focus on some specific  
6 language with you now. Could we go to 2:21. Is  
7 it ready to play? All right. Now we'll play  
8 some clips and I'll ask you some questions.  
9 (Video played as follows:  
10 "Opioid abuse is a nationwide  
11 epidemic. Every 19 minutes someone dies  
12 from an unintentional drug overdose and  
13 when it comes to overdose deaths caused  
14 by prescription drugs, nearly three out  
15 of four are caused by painkillers. The  
16 number of deaths involving opioids now  
17 outnumbers those from cocaine and heroin  
18 combined. Regulations" --)  
19 MR. BUCHANAN: You can press  
20 pause.  
21 BY MR. BUCHANAN:  
22 Q. You recall that portion of the  
23 video, ma'am?  
24 A. I do.



<p style="text-align: right;">Page 717</p> <p>1 Q. You were involved in its 2 preparation?</p> <p>3 A. I was involved in -- I didn't -- 4 I didn't draft the wording for it, but I was -- 5 I reviewed it before, yes.</p> <p>6 Q. I think you told us a few minutes 7 ago you reviewed and endorsed it, right?</p> <p>8 A. Yes.</p> <p>9 Q. Okay. Content was accurate when 10 written?</p> <p>11 MS. BANNI: Object to form.</p> <p>12 THE WITNESS: I don't know if you 13 say accurate. It was -- it sounded -- 14 it sounded right when I reviewed it.</p> <p>15 BY MR. BUCHANAN:</p> <p>16 Q. Right, I mean, you were certainly 17 trying to make sure that it was accurate when 18 you were putting it out and distributing it on a 19 website for pharmacies around the country, 20 right?</p> <p>21 MS. BANNI: Object to form.</p> <p>22 THE WITNESS: We did not put it 23 out and distribute it on a website. 24 That was done by NABP.</p>	<p style="text-align: right;">Page 719</p> <p>1 another doctor, right?</p> <p>2 MS. BANNI: Object to form.</p> <p>3 THE WITNESS: These were things 4 that we had been told by DEA were 5 issues, yes.</p> <p>6 BY MR. BUCHANAN:</p> <p>7 Q. And we see people on the screen, 8 and these are people that, could we agree, are 9 everyday folks?</p> <p>10 MS. BANNI: Object to form.</p> <p>11 MS. KOSKI: Object to form.</p> <p>12 THE WITNESS: I guess, yeah.</p> <p>13 MR. BUCHANAN: Okay. Let's play 14 from 4:56.</p> <p>15 (Video played as follows: 16 "For every unintentional overdose 17 death from opioids in 2010, there were 18 733 nonmedical users. Emergency room 19 visits resulting from pharmaceutical 20 abuse with no other type of drug or 21 alcohol involved almost doubled between 22 2004 and 2010.")</p> <p>23 MR. BUCHANAN: Press pause, 24 please.</p>
<p style="text-align: right;">Page 718</p> <p>1 BY MR. BUCHANAN:</p> <p>2 Q. Well, the anti-diversion working 3 group issued a press release, right?</p> <p>4 A. I believe Mallinckrodt issued a 5 press release and noted everybody on there, yes.</p> <p>6 Q. Right. And you endorsed its 7 content when it was released, correct?</p> <p>8 MS. BANNI: Object to form.</p> <p>9 THE WITNESS: Yes.</p> <p>10 BY MR. BUCHANAN:</p> <p>11 Q. Even sent it around to your peers 12 in the firms to show it to them, right?</p> <p>13 A. Right. It was something that I 14 was proud that we had -- we had done.</p> <p>15 Q. Okay. Let's go to 4:56, and 16 we're kind of scrubbing through the images. 17 Does that refresh your recollection in terms of 18 its content?</p> <p>19 A. Yes.</p> <p>20 Q. People walking up to a counter, 21 red flags, cash customers, people walking in in 22 groups?</p> <p>23 A. Mm-hmm.</p> <p>24 Q. People going from one doctor to</p>	<p style="text-align: right;">Page 720</p> <p>1 BY MR. BUCHANAN:</p> <p>2 Q. Big problem, can we agree?</p> <p>3 MS. BANNI: Object to form.</p> <p>4 THE WITNESS: Big problem, there 5 is an addiction problem in the United 6 States, yes.</p> <p>7 BY MR. BUCHANAN:</p> <p>8 Q. For every opioid death in 2010, 9 there were 733 nonmedical users of those drugs, 10 right?</p> <p>11 A. That's what this -- the data 12 showed. I'm not sure where the data came from, 13 I don't recall, but it was probably from a 14 regulatory agency.</p> <p>15 Q. Data you endorsed as accurate at 16 that point in time personally, correct?</p> <p>17 MS. BANNI: Object to form.</p> <p>18 THE WITNESS: Yes.</p> <p>19 BY MR. BUCHANAN:</p> <p>20 Q. Data you endorsed as accurate on 21 behalf of the anti-diversion working group, 22 correct?</p> <p>23 MS. BANNI: Object to form.</p> <p>24 THE WITNESS: Yes.</p>

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1 BY MR. BUCHANAN:  
2 Q. We've seen stats on opioid  
3 deaths. You're familiar there's stats out  
4 there, right?  
5 A. Yes.  
6 Q. As of this point in time, you had  
7 the knowledge that for every death there were  
8 733 people who were using opioids for nonmedical  
9 use, right?  
10 MS. BANNI: Objection, beyond the  
11 scope.  
12 THE WITNESS: It's all stats that  
13 are out there. We took the stats as  
14 they were. I don't know what the  
15 details were before into them and how  
16 they were obtained, but we assumed they  
17 were accurate based on the source.  
18 BY MR. BUCHANAN:  
19 Q. You certainly were trying to  
20 convey accurate information, correct?  
21 A. Yes, we were.  
22 Q. And, to the best of your  
23 knowledge, ma'am, you did so, correct?  
24 A. Yes.

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1 Q. Okay. Let's go forward now to  
2 8:25. And we see kind of interspersed with  
3 facts these scenarios with individuals  
4 approaching a pharmacy counter, fair?  
5 A. Yes.  
6 Q. Okay.  
7 MR. BUCHANAN: Could you play  
8 8:25.  
9 (Video played as follows:  
10 "America's biggest drug problem  
11 isn't on the streets, it's in our  
12 medicine cabinets. Seventy percent of  
13 Americans are taking at least one  
14 prescription drug and more than 50% are  
15 on at least two. Among young people who  
16 abuse prescription medications, 70% get  
17 them from family or friends.")  
18 MR. BUCHANAN: Let's pause.  
19 BY MR. BUCHANAN:  
20 Q. America's drug problem isn't on  
21 the streets, it's in our medicine cabinet.  
22 Did you hear that?  
23 A. I did.  
24 Q. True statement when made, right?

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1 MS. VANNI: Object to form.  
2 THE WITNESS: It's one of the  
3 things that's outlined on DEA's website  
4 and why they do their national take back  
5 days now, yes.  
6 BY MR. BUCHANAN:  
7 Q. And the manufacturers who you  
8 worked with in the anti-diversion working group  
9 endorse that as a true statement of the state of  
10 affairs as of 2014 when this video was prepared,  
11 correct?  
12 MS. VANNI: Objection.  
13 THE WITNESS: Yes, there's always  
14 independent thought and people who will  
15 abuse and take things in ways they  
16 shouldn't.  
17 BY MR. BUCHANAN:  
18 Q. America's drug problem isn't on  
19 the streets, it's in our medicine cabinets,  
20 right?  
21 A. In that particular case, yes,  
22 when we were directing to pharmacies, yes, that  
23 is the case.  
24 MR. BUCHANAN: Let's go to nine

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1 minutes and three seconds and play that  
2 portion.  
3 (Video played as follows:  
4 "More Americans abuse  
5 prescription drugs than the number of  
6 cocaine, hallucinogen, methamphetamine  
7 and heroin abusers combined. The  
8 pharmacy" --)  
9 MR. BUCHANAN: Let's pause there.  
10 BY MR. BUCHANAN:  
11 Q. More Americans abuse prescription  
12 drugs than cocaine, hallucinogens,  
13 methamphetamine and heroin abusers combined.  
14 Did you hear that, ma'am?  
15 A. I did.  
16 Q. To your knowledge in 2014, that  
17 was a true statement you were making through the  
18 anti-diversion working group for this video,  
19 correct?  
20 A. Those were statements that have  
21 would come from DEA or CDC or a regulator, so I  
22 would assume, yes.  
23 Q. You certainly wouldn't endorse  
24 them as appropriate or true if they weren't

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1 true, right?  
2 MS. VANNI: Object to form.  
3 THE WITNESS: Yes.  
4 BY MR. BUCHANAN:  
5 Q. To the best of your knowledge,  
6 ma'am, as a person who was on this committee to  
7 review and endorse this video, those were true,  
8 right?  
9 A. Those --  
10 MS. VANNI: Object to form.  
11 THE WITNESS: Those were publicly  
12 available.  
13 BY MR. BUCHANAN:  
14 Q. To the best of your knowledge,  
15 they were true?  
16 A. I wasn't in a position to make a  
17 determination if they were true. They were  
18 publicly available. I didn't have access to the  
19 data that was used to compile that information,  
20 so I can't say they were 100% true. I can only  
21 make a assumption based on the viability of the  
22 sources that they came from.  
23 Q. America's drug problem isn't on  
24 the streets, it's in our medicine cabinets,

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1 right?  
2 A. It's in a lot of places, but,  
3 yes, that's one of them.  
4 Q. What you put in the video is that  
5 it wasn't on the streets, it was in people's  
6 medicine cabinets, correct, ma'am?  
7 MS. VANNI: Object to form.  
8 THE WITNESS: Because that's what  
9 the video was focused on.  
10 BY MR. BUCHANAN:  
11 Q. Is that what you put on the  
12 video? Not because, not why --  
13 MS. VANNI: Let her answer her  
14 question -- her answer.  
15 BY MR. BUCHANAN:  
16 Q. Not because, not why. Stay with  
17 my questions.  
18 What you put in the video, ma'am,  
19 was that America's drug problem isn't on the  
20 street, it's in our medicine cabinets, correct?  
21 MS. VANNI: Object to form.  
22 THE WITNESS: Yes, the video is  
23 directed to its audience.  
24 MR. BUCHANAN: Okay. Let's go to

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1 10:31 to 10:46.  
2 (Video played as followed:  
3 "One in four teens reports having  
4 misused a prescription drug at least  
5 once. That translates to 5 million  
6 teenagers, a 33% increase over the past  
7 five years.")  
8 MR. BUCHANAN: Let's pause.  
9 BY MR. BUCHANAN:  
10 Q. 33% increase in teen abuse of  
11 prescription drugs between 2009 and 2014.  
12 You saw that reference, ma'am?  
13 A. Yes, I did.  
14 Q. During the same period of time  
15 that Mr. -- after Mr. Rannazzisi and the DEA had  
16 sent you a notice saying everybody has got to  
17 maintain effective controls against diversion,  
18 right?  
19 A. Yes.  
20 Q. And where we've gotten to by 2014  
21 is that America's drug problem isn't on the  
22 street, it's in medicine cabinets, right?  
23 MS. VANNI: Object to form.  
24 THE WITNESS: That was the --

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1 those were the statistics that were in  
2 the video, yes.  
3 MR. BUCHANAN: Okay. Well, let's  
4 go now to towards the end, 11:41.  
5 BY MR. BUCHANAN:  
6 Q. Okay. And this video was going  
7 out to pharmacies, right?  
8 A. That was the focus.  
9 MR. BUCHANAN: Okay. Could you  
10 roll it from here, please.  
11 (Video played as follows:  
12 "Who is responsible? Yes, it's  
13 the culture. Yes, it's the doctor or  
14 prescriber. Yes, it's law enforcement.  
15 Yes, it's the state boards. But you,  
16 the pharmacist, have a corresponding  
17 responsibility. You play a critical  
18 role.")  
19 MR. BUCHANAN: Pause, please.  
20 BY MR. BUCHANAN:  
21 Q. Did you hear who was listed as  
22 who's responsible?  
23 A. Yes.  
24 Q. Who did the anti-diversion

<p style="text-align: right;">Page 729</p> <p>1 working group highlight as responsible for this                  2 situation, ma'am?                  3 A. Many aspects of the supply                  4 change.                  5 Q. I'm sorry. I didn't hear                  6 manufacturers or distributors mentioned, did                  7 you?                  8 MS. VANNI: Object to form.                  9 THE WITNESS: No, because we had                  10 DEA controls in place.                  11 BY MR. BUCHANAN:                  12 Q. In this video in terms of who is                  13 responsible for this, the anti-diversion working                  14 group, Qualitest, other manufacturers, other                  15 distributors point the finger at culture, right?                  16 MS. VANNI: Object to form.                  17 BY MR. BUCHANAN:                  18 Q. You saw that?                  19 A. That's what it says, yes.                  20 Q. Pointed the finger at the DEA,                  21 right?                  22 MS. VANNI: Objection.                  23 THE WITNESS: Yes.                  24 BY MR. BUCHANAN:</p>	<p style="text-align: right;">Page 731</p> <p>1 THE WITNESS: Manufacturers that                  2 comply with the regulations are not                  3 contributing to the problem.                  4 BY MR. BUCHANAN:                  5 Q. Did you see any reference to                  6 manufacturers' influence on state boards?                  7 MS. VANNI: Objection.                  8 THE WITNESS: No, I would not                  9 think that that would be applicable to                  10 this.                  11 BY MR. BUCHANAN:                  12 Q. Did you see any reference to                  13 distributors' influence on state boards?                  14 A. No.                  15 Q. Did you see any reference to our                  16 industry associations that have worked to change                  17 the treatment of pain so that these drugs could                  18 be prescribed more broadly, did you see any                  19 reference to that as a responsibility?                  20 MS. VANNI: Objection.                  21 THE WITNESS: No.                  22 BY MR. BUCHANAN:                  23 Q. Did you see any reference to                  24 distributors who had no suspicious order</p>
<p style="text-align: right;">Page 730</p> <p>1 Q. Pointed the finger at doctors,                  2 right?                  3 A. Yes, definitely.                  4 MS. VANNI: Objection.                  5 BY MR. BUCHANAN:                  6 Q. And pointed the finger at state                  7 boards?                  8 MS. VANNI: Objection.                  9 THE WITNESS: Yes, definitely.                  10 BY MR. BUCHANAN:                  11 Q. Okay. And pointed the finger at                  12 pharmacists, right?                  13 MS. VANNI: Objection.                  14 THE WITNESS: Yes, definitely.                  15 BY MR. BUCHANAN:                  16 Q. Missed a few big players in the                  17 supply chain; we agree?                  18 MS. VANNI: Objection.                  19 THE WITNESS: I would not agree.                  20 BY MR. BUCHANAN:                  21 Q. We could agree that manufacturers                  22 aren't referenced in terms of their roles in                  23 influencing state boards, right?                  24 MS. VANNI: Objection.</p>	<p style="text-align: right;">Page 732</p> <p>1 monitoring programs for years and years and                  2 years?                  3 MS. VANNI: Objection.                  4 THE WITNESS: No.                  5 BY MR. BUCHANAN:                  6 Q. Did you see any reference to                  7 manufacturers who had no such responsibility?                  8 MS. VANNI: Objection.                  9 THE WITNESS: No.                  10 BY MR. BUCHANAN:                  11 Q. Did you see any reference to the                  12 30 plus million dollars Endo paid to the NIPC to                  13 run programs to expand the market for pain?                  14 MS. VANNI: Objection, beyond the                  15 scope, argument.                  16 THE WITNESS: No, and I didn't                  17 see any reference either to product                  18 imported illegally or to any other                  19 scenario, independent thought, any other                  20 scenario that causes abuse and                  21 addiction. That was not the focus of                  22 this video.                  23 BY MR. BUCHANAN:                  24 Q. Who is responsible? You endorsed</p>

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1 this?

2 A. I did.

3 Q. We have your letter, ma'am, from

4 October 18, 2013.

5 Do you recall that?

6 A. I recall the date. I can't

7 recall what the letter said, but yes.

8 Q. That's where you told all of your

9 customers that we all have this responsibility,

10 right?

11 A. Yes.

12 MS. VANNI: Object to form.

13 BY MR. BUCHANAN:

14 Q. We all have this responsibility,

15 manufacturers, correct?

16 A. Yes.

17 Q. Distributors, correct?

18 MS. VANNI: Objection.

19 THE WITNESS: Yes.

20 MS. VANNI: Objection.

21 THE WITNESS: And I consider

22 putting that out there to be going above

23 and beyond, and that's, again, something

24 that I have always wanted to do.

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1 MR. BUCHANAN: Could we go to the

2 next slide, please, let's finish it.

3 (Video played as follows:

4 "When you are in that moment of

5 truth, will you recognize and act upon

6 the red flag?")

7 MR. BUCHANAN: Let's pause.

8 BY MR. BUCHANAN:

9 Q. So we could agree that in terms

10 of who has the responsibility, manufacturers and

11 distributors and others that had no suspicious

12 order monitoring programs or efforts to prevent

13 diversion were not listed, correct?

14 MS. VANNI: Object to form.

15 BY MR. BUCHANAN:

16 Q. We can agree on that?

17 A. We can agree that everyone has a

18 responsibility to abide by the regulations.

19 Q. Okay. We can agree that when

20 those that had the responsibility for this

21 situation, who is responsible was the question.

22 Do you recall that?

23 MS. VANNI: Object to form.

24 BY MR. BUCHANAN:

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1 Q. Do you recall that question in

2 the video?

3 A. In this particular video, yes.

4 Q. Who is responsible?

5 A. Yes.

6 Q. Okay. We could agree that the

7 Cardinal Healths, the Actavis, the McKessons,

8 the Mallinckrodt, the AmerisourceBergens and

9 the Qualitest, who sponsored the video, are not

10 listed in any way as having responsibility for

11 this, correct?

12 MS. VANNI: Object to form.

13 THE WITNESS: We have a

14 responsibility to comply with the

15 regulation.

16 BY MR. BUCHANAN:

17 Q. Do you have my question, ma'am.

18 When the question was asked in the video --

19 A. They are not listed in the video.

20 Q. That's right. But yet you knew,

21 you knew when you sent your letter in February

22 of 2013 that you had a responsibility as

23 Qualitest, correct?

24 MS. VANNI: Object to form.

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1 THE WITNESS: Of course. That's

2 why we did comply.

3 BY MR. BUCHANAN:

4 Q. Distributors had that

5 responsibility, correct?

6 A. Yes.

7 Q. And if anyone broke that supply

8 -- that closed system, heart-wrenching

9 consequences could occur, right?

10 A. That's what my letter said, yes.

11 Q. Okay. Now, let's focus on a few

12 other points you did in examination with

13 counsel.

14 MR. BUCHANAN: What do we have

15 time-wise?

16 THE VIDEOGRAPHER: Seven minutes.

17 We're at 1:13. Do you want me to go

18 off?

19 MR. BUCHANAN: No, no, we're

20 fine.

21 BY MR. BUCHANAN:

22 Q. Just want to circle back on some

23 of the questions about Anda, specifically this

24 interaction you had with DEA in the summer of



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1 2007.  
2 Do you recall that, ma'am?  
3 A. Yes.  
4 Q. Okay. I think -- I think defense  
5 counsel characterized it as an invitation?  
6 A. Yes.  
7 Q. You were invited?  
8 A. Yes.  
9 Q. Didn't they say they wanted to  
10 talk to you about serious concerns?  
11 MS. KOSKI: Object to form.  
12 THE WITNESS: DEA did, yes.  
13 BY MR. BUCHANAN:  
14 Q. They told you they wanted to talk  
15 to you about serious concerns because certainly  
16 about certain orders, but also your suspicious  
17 order monitoring system, correct?  
18 MS. KOSKI: Object to form.  
19 THE WITNESS: Anda's suspicious  
20 order monitoring system.  
21 BY MR. BUCHANAN:  
22 Q. Yeah, the year was a little  
23 confusing there, but Anda's suspicious order  
24 monitoring system, correct?

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1 A. Yes.  
2 Q. And you parsed the language  
3 closely in some areas with counsel. I'd like  
4 you now to look at Exhibit 32 that was marked in  
5 examination. I don't have the ability to pull  
6 it up on the screen for you, ma'am. It's the  
7 e-mail exchange on July 16th, 2007 between  
8 yourself and Diane -- Ms. Miranda?  
9 A. Yes.  
10 Q. Okay. This is an interaction  
11 phone call you had with a Mr. Mapes from the  
12 DEA.  
13 A. Hold on. I just have one page.  
14 Q. This is an interaction you had  
15 with a Mr. Mapes from the DEA, correct?  
16 A. It is a documented detail of that  
17 descript -- that phone call, yes.  
18 Q. You got a phone call, right?  
19 A. Yes.  
20 Q. First call was, hey, does Watson  
21 own Anda now, right?  
22 A. Correct.  
23 Q. Okay. He then indicated he had  
24 concerns.

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1 Did I read that correctly?  
2 A. He did indicate that.  
3 Q. About Anda, that he would like to  
4 discuss, okay.  
5 You understood he had concerns?  
6 A. That's yes.  
7 Q. Okay. You started to read I  
8 think the first sentence in the bottom of page 1  
9 of Exhibit 32, Bates stamp 959. "Mr. Mapes then  
10 went on to say that since then, they have seen a  
11 steady increase in Anda's sales of hydrocodone,  
12 to the point of these sales being extremely  
13 questionable."  
14 Do you recall that?  
15 A. These were the -- yes, it's a  
16 summary of what he was saying during the call.  
17 Q. And he said that many of the  
18 retail pharmacies that you were selling to were  
19 feeding the drugs to illegal internet  
20 pharmacies, right?  
21 MS. KOSKI: Object to form.  
22 THE WITNESS: That's what he  
23 said, yes.  
24 BY MR. BUCHANAN:

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1 Q. He then said he had questions  
2 about the effectiveness of Anda's suspicious  
3 order monitoring system, correct?  
4 A. He asked about the effectiveness,  
5 which I couldn't really comment on, having not  
6 worked there.  
7 Q. Yeah, and that was interesting.  
8 I think you were asked a question by defense  
9 counsel about did Anda have its own DEA  
10 compliance group.  
11 Do you recall that?  
12 A. Yes.  
13 Q. When the time came after you  
14 were -- I think you said summoned in your  
15 characterization of this?  
16 A. I did.  
17 Q. After you were summoned to go and  
18 meet with the DEA in Washington, who came with  
19 you from DEA compliance at Anda?  
20 A. I believe Michael Cochrane.  
21 Q. CEO?  
22 A. I'm not sure what his title was,  
23 but he was the person who at the time I was told  
24 handled DEA compliance.

<p style="text-align: right;">Page 741</p> <p>1 Q. Okay. Well, let's look at your  2 writing in Exhibit 2. Exhibit 2 is your summary  3 of your experience at Ciba-Geigy, Watson,  4 Qualitest, et cetera; do you recall?  5 A. Yes.  6 Q. And you note in the middle of the  7 description --  8 MR. BUCHANAN: Could we pull up  9 1146.2 and go to the Watson entry in the  10 middle of the paragraph.  11 BY MR. BUCHANAN:  12 Q. It says, "However, Watson  13 purchased Anda and certainly afterward, Anda was  14 summoned to DEA as a result of their lack of a  15 robust SOM program."  16 Did I read that correctly?  17 A. You did.  18 Q. "I did not support Anda from a  19 DEA perspective as they had come to Watson with  20 their own DEA person."  21 And it notes, however, you were  22 asked to be their DEA representative for the  23 meeting in HQ.  24 Did I read that correctly?</p>	<p style="text-align: right;">Page 743</p> <p>1 A. For cause.  2 Q. For cause. It wasn't just a  3 regular distributor meeting that you talked  4 about having -- being aware of that was  5 happening in the industry, correct?  6 A. Actually, it was a bad choice of  7 words.  8 Q. You've told us about several  9 words that I think you'd rather recast in your  10 oral testimony, but what you wrote when you were  11 characterizing your experience, on reflection at  12 Watson, was that the DEA meeting was for cause,  13 correct?  14 A. That's what I wrote, yes.  15 Q. And that "immediate action was  16 required," that's what you wrote, right?  17 A. Yes.  18 Q. "Immediate action required,"  19 correct?  20 A. That's what I wrote, yes.  21 Q. Not suggested, right?  22 A. That's what I wrote, yes.  23 Q. Not just to go above and beyond,  24 right?</p>
<p style="text-align: right;">Page 742</p> <p>1 A. Yes.  2 Q. And what you listed for the  3 people that you went with to that meeting were a  4 representative of the legal department, correct?  5 You can read it in the next  6 sentence.  7 A. Yes.  8 Q. What you listed --  9 A. I don't know who the legal person  10 was.  11 Q. You went with legal and the  12 individual who at the time was the president of  13 Anda, correct?  14 A. Yes.  15 Q. And we talked about the binder  16 you got, and I won't revisit that.  17 But then you note, however --  18 well, actually, we probably should. "DEA  19 presented and provided a binder as they have  20 done for most companies at this point" in time.  21 Do you see that?  22 A. Yes.  23 Q. Okay. "However, in Anda's case  24 the DEA meeting was" what?</p>	<p style="text-align: right;">Page 744</p> <p>1 A. Yes.  2 Q. Required?  3 A. As written.  4 Q. That's what you wrote?  5 A. As written, yes.  6 Q. Okay. Anda then revamped their  7 program and we conveyed the results to the DEA.  8 Did I read that correctly?  9 A. You did.  10 Q. Okay. Mr. Mapes, you referenced  11 an interaction with him in this 2007 period of  12 time.  13 Is that the same Mr. Mapes that  14 Qualitest brought in to evaluate their program  15 in 2008 that we looked at yesterday?  16 A. Yes, I believe so.  17 Q. That identified inadequacies with  18 the SOM program at Qualitest?  19 MS. VANNI: Object to form, and I  20 think we're at time.  21 THE WITNESS: Again, I'm not  22 sure.  23 BY MR. BUCHANAN:  24 Q. What's that?</p>

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1 A. Again, I'm not sure.  
2 MR. BUCHANAN: Okay. If that's  
3 the case, is that accurate? Okay. Let  
4 me -- for to correct one thing on the  
5 record, counsel, I'm just going to mark  
6 this and you can have it.  
7 (Document marked for  
8 identification as Par-Norton Deposition  
9 Exhibit No. 41.)  
10 MR. BUCHANAN: This is Exhibit  
11 41. It's the -- I'm passing it over to  
12 the witness.  
13 I'll represent to counsel that  
14 Exhibit 41 is the remainder of the  
15 spreadsheet data that Endo/Qualitest has  
16 pointed plaintiffs' counsel to as  
17 representative of -- as containing the  
18 sales and shipping data of the company's  
19 various controlled substances. That  
20 Bates number should correlate with the  
21 summary exhibit, which is Exhibit 4, as  
22 a data source.  
23 Thank you, ma'am. I'm told I'm  
24 out of time.

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1 THE WITNESS: Thank you.  
2 MR. BUCHANAN: I appreciate your  
3 indulgence. Off the record.  
4 THE VIDEOGRAPHER: The time is  
5 11:56. Off the record.  
6 (Brief recess.)  
7 THE VIDEOGRAPHER: 12:06, back on  
8 the record.  
9 MR. BUCHANAN: Ms. Norton, I'm  
10 advised that I'm out of time. I have no  
11 further questions at this time.  
12 Counsel, your witness.  
13 MS. VANNI: I have no questions  
14 at this time. Thank you.  
15 THE VIDEOGRAPHER: The time is  
16 now 12:06 p.m. This concludes today's  
17 portion of the deposition of Tracey  
18 Norton. We are now off the record.  
19 (Witness excused.)  
20 ---  
21  
22  
23  
24

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1 C E R T I F I C A T I O N  
2 I, MARGARET M. REIHL, a  
3 Registered Professional Reporter,  
4 Certified Realtime Reporter, Certified  
5 Shorthand Reporter, Certified LiveNote  
6 Reporter and Notary Public, do hereby  
7 certify that the foregoing is a true and  
8 accurate transcript of the testimony as  
9 taken stenographically by and before me  
10 at the time, place, and on the date  
11 hereinbefore set forth.  
12 I DO FURTHER CERTIFY that I  
13 am neither a relative nor employee nor  
14 attorney nor counsel of any of the  
15 parties to this action, and that I am  
16 neither a relative nor employee of such  
17 attorney or counsel, and that I am not  
18 financially interested in the action.  
19  
20  
21 -----  
22 Margaret M. Reihl, RPR, CRR, CLR  
23 CSR #XI01497 Notary Public  
24

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ACKNOWLEDGMENT OF DEPONENT

I, TRACEY L. NORTON, do hereby  
certify that I have read the foregoing  
pages, and that the same is a correct  
transcription of the answers given by me  
to the questions therein propounded,  
except for the corrections or changes in  
form or substance, if any, noted in the  
attached Errata Sheet.

TRACEY L. NORTON                      DATE

Subscribed and sworn to before me this

\_\_\_\_\_ day of \_\_\_\_\_, 2018.

My commission expires: \_\_\_\_\_

\_\_\_\_\_  
Notary Public